

COMMON POOL GOODS AND NEW TECHNOLOGY ADOPTION: HOW CANADA CAN
IMPLEMENT NEW VACCINOLOGY STRATEGIES RELATED TO JOHNE'S DISEASE

A Thesis Submitted to the
College of Graduate and Postdoctoral Studies
In Partial Fulfillment of the Requirement
For the Degree of Master in Public Policy
In the Johnson-Shoyama Graduate School of Public Policy
University of Saskatchewan
Saskatoon

By

JASROOP SINGH GOSAL

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Dean
College of Graduate and Postdoctoral Studies
University of Saskatchewan
116 Thorvaldson Building, 110 Science Place
Saskatoon, Saskatchewan S7N 5C9
Canada

Abstract

With a growing population, there are risks to food security that would negatively affect a great proportion of the global population. Dairy is a particularly valuable dietary resource that feeds a large proportion of the global population. One key potential constraint on growth of milk production is disease. Disease management is crucial to preserving food security and profits for the public and private markets, respectively. Johne's Disease (JD) is a contagious, chronic and often fatal infection that primarily affects the small intestines of ruminants. Disease management currently includes solutions such as cull-and-kill, best-management practices, vaccinations, and disease testing kits. Current vaccines and tests for JD result in false positive results for tuberculosis (TB), caused by the pathogens *Mycobacterium tuberculosis* (M. tb, the human variant) and *Mycobacterium bovis* (M. bovis, the bovine variant). When positive TB results are triggered, either due to the presence of the disease or due to false-positives, governments quarantine the suspected product. Often this involves quarantine of infected farms, extermination of the animals, extended-cease production orders for infected farms and withdrawals and destruction of any suspected contaminated products from the market. The feasibility of a range of potential solutions is explored. The capacity of various institutions and actors to implement any solution is explained using the Institutional Analysis and Development Framework. Maintaining food security is a concern for the broader public, but the benefits and costs of JD management are distributed among various actors in the private market as well, making JD management a common pool good. The thesis illuminates a range of disease management options, assesses the incentives and impacts of various options for controlling JD and preserving food security, and offers insights into the best way to implement the optimal solution.

Acknowledgements

I would like to thank my thesis advisor Dr. Peter W.B. Phillips of the Johnson-Shoyama Graduate School of Public Policy at The University of Saskatchewan. The door to Prof. Phillips office was always open whenever I ran into any issues or had a question about my research or writing. He consistently allowed this paper to be my own work but steered me in the right direction whenever he thought I needed it.

I would also like to acknowledge Dr. Albert Ugochukwu of the Johnson-Shoyama Graduate School of Public Policy at the University of Saskatchewan as the second reader of this thesis, and I am gratefully indebted to him for his very valuable comments on this thesis. Finally, I must express my profound gratitude to my family, parents and to my wife for providing me with unfailing support and continuous encouragement throughout my years of study and through the process of researching and writing this thesis. This accomplishment would not have been possible without them. Thank you.

Jasroop Singh Gosal

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Abbreviations

BSE: Bovine Spongiform Encephalopathy

CCVB: The Canadian Centre for Veterinary Biologics

CFIA: The Canadian Food Inspection Agency

CRP: Chairperson of the Review Panel

DIVA: Differentiating Infection in Vaccinated Animals

ELISA: Enzyme-Linked Immunosorbent Assay

EU: European Union

IAD: Institutional Analysis and Development

JD: Johne's Disease

NAHMS: National Animal Health Monitoring System

OECD: Organisation for Economic Co-operation and Development

OIE: World Organization for Animal Health

OIESRDK: OIE Secretariat for Registration of Diagnostic Kits

ReVAMP: Reverse Vaccinology

TB: Tuberculosis

UK: United Kingdom

US: United States

USDA: United States Department of Agriculture

VIDO-InterVac: Vaccine and Infectious Disease Organization-International Vaccine Centre

WHP: Within Herd Prevalence

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Section 1:

Introduction

With a growing global population, there are risks to food security that would negatively affect a great proportion of the global population. Milk is a particularly valuable dietary resource that feeds a large proportion of the global population and provides essential nutrients – calcium, protein, iodine, potassium, phosphorus and vitamins B2 and B12. Globally, the dairy bovine sector is one of the most widely produced and valuable agricultural commodities, with 2013 production of 770 billion litres of milk valued at 328 billion USD (Food and Agriculture Organization of the United Nations, 2014). Milk production is a key component of any food security strategy as milk contains energy, protein, and vital micronutrients (Westenhöfer, 2013). As of 2016, dairy manufacturing shipments from Canada totaled C\$399 million, with a dairy cattle population of 1.4 million head (Agriculture and Agri-Food Canada, 2018).

One key potential constraint on growth of milk production is infectious disease. Disease management is crucial to preserving food security and profits for the public and private markets respectively. When food security is secured, both the society and economy benefits.

Johne's Disease (JD) is a contagious, chronic, incurable enteric, and often fatal infection that primarily affects the small intestines of ruminants (Garcia and Shalloo, 2015). In 2007, an estimated 68% of dairy herds in the US had at least 1 cow with JD (Corbett et al., 2018). Because of the widespread prevalence there is a range of impacts on certain populations and regions (Espejo, Godden, Hartmann, and Wells, 2012). The chronic enteritis in ruminants is caused by *Mycobacterium avium* subspecies *Paratuberculosis* (MAP) (Garcia and Shalloo, 2015). The main impact of JD in the dairy sector is economic losses directly associated with premature culling, as well as reduced milk production (Raizman et al., 2007). Milk production from dairy cows affected with Johne's disease has been estimated to drop by 590 kg in the third lactation and up to 1,270 kg in the fourth lactation (Alberta Minister of Agriculture and Forestry, 2015). JD also negatively affects the well-being of cattle; as JD progresses, it slowly causes weight loss and eventual death. Currently, practical treatment is not available (Espejo, Godden, Hartmann, and Wells, 2012). Ignoring the disease is not a viable long-term strategy. Beyond the economic

and animal welfare effects, there are some suggestions that JD may contribute to human health issues (Feller et al., 2007). The organism that causes Johne's disease is not currently known to cause disease in humans, but it has been detected in humans with Crohn's disease, as have numerous other bacteria and viruses. This call for effective risk mitigation strategies.

Existing disease management strategies currently in practice include cull-and-kill, best-management practices (e.g. separation of heifers from calf), vaccinations, and disease testing kits, or a combination. Current vaccines for Johne's disease have been shown to give false positive results for tuberculosis (TB), caused by the pathogens *Mycobacterium tuberculosis* (M. TB the human variant) and *Mycobacterium bovis* (M. bovis, the bovine variant). Humans can contract TB from raw milk contaminated with M.bovis. TB is one of the deadliest diseases facing mankind. In a report published by The World Health Organization, an estimated 1.8 billion people—one quarter of the world's population—are currently infected with the bacteria that causes TB and 10 million people fell ill from TB and 1.6 million died last year (2019).

Most domestic food safety systems and international trade regimes have measures in place to address risks related to TB in live cattle and meat products. The most common test is the enzyme-linked immunosorbent assay, also called ELISA, which detects and measures antibodies in the blood. When an animal is vaccinated using current vaccines for JD, some ELISA tests trigger a positive test result for TB because of the similar antibodies. A positive TB test triggered due to the presence of JD vaccine markers is known as a false positive. When positive results are triggered, either due to the presence of the disease or due to false-positives, governments quarantine the suspected product. Often this involves quarantine of infected farms, extermination of the animals, extended cease production orders for infected farms, and withdrawals and destruction of any suspected contaminated products from the market. The results are a loss of profit, food insecurity, and other negative trade implications such as border closures. Any new vaccine will need to effectively handle this risk.

This thesis begins with a discussion of the nutrition and safety challenges facing policy makers. The discussion will touch on the need for nutritious, safe, and secure food, and the evidence of the links between JD and decreased milk production. Following this review, I will illustrate the national and international mechanisms and methods used to control JD. The thesis uses the theory of common pool goods to examine the policy challenges of developing vaccines. This will lead to an analysis and explanation of a range of potential policy scenarios that will be

used to establish the conditions for a best-case scenario for all actors (government, the general public, vaccine producers, and milk producers). This best-case scenario is used to discuss policy options. Regardless of the technical aspects of the strategy chosen, there is need for effective communication and education of vaccine end users on vaccine and DIVA test producers, involving veterinarians, the government, and marketing agents/companies. The thesis ends with a concluding chapter.

Section 2:

Background

Globally, the bovine dairy sector is one of the most widely distributed and valuable sources of agricultural commodities, with production of 770 billion litres of milk valued at 328 billion USD in 2013 (Food and Agriculture Organization of the United Nations 2014). The market is projected to grow by 177 million tonnes by 2025 (Food and Agriculture Organization of the United Nations 2014). Milk production is a key component of any food security strategy as milk contains energy, protein, and vital micronutrients (Westenhöfer, 2013). As of 2016 statistics, dairy manufacturing shipments from Canada totaled C\$15.2 billion, with a dairy cattle population of 1.4 million head (Agriculture and Agri-Food Canada, 2018). One potential constraint on that growth is disease infestation.

Johne's Disease and TB are found in ruminants that produce milk. If a bovine ruminant contracts JD, milk production is reduced (Alberta Minister of Agriculture and Forestry, 2015), and the health of the animal is compromised. Given the overall importance of milk in our global diet, these effects jeopardize food security.

JD is contracted when ruminants consume feed and water contaminated with manure from infected animals. The disease is not immediately detectable by the current tests. The disease becomes apparent when shedding and diarrhea is observed. Viral shedding refers to the expulsion and release of virus progeny following successful reproduction during a host-cell infection. Once replication has been completed and the host is exhausted of all resources in making viral progeny, the viruses may begin to leave (Donat et al., 2014). In the case of ruminants, the virus is expelled in body excretions, both from the nose and mouth and digestive tract.

2.1: Stages of Johne's Disease

Figure 2.1 shows an illustration of the protracted nature in terms of the number of stages before clinical signs of Johne's disease visibly manifest in the animal. Animals can get infected as early as a few months after birth, while clinical signs only show at a later stage – between 2 to 6 years of age (Hendrick and Douma, 2006). According to Chiodini et al. (1984) and Sockett et al.

(1992, p.152), clinical signs are contingent on ‘age at infection’ and ‘dosage of the organism’. Given the time lag between infection and display of clinical signs, cattle infected at a mature age would have a low chance of showing clinical signs before the animal is culled (Whitlock and Buergelt, 1996).

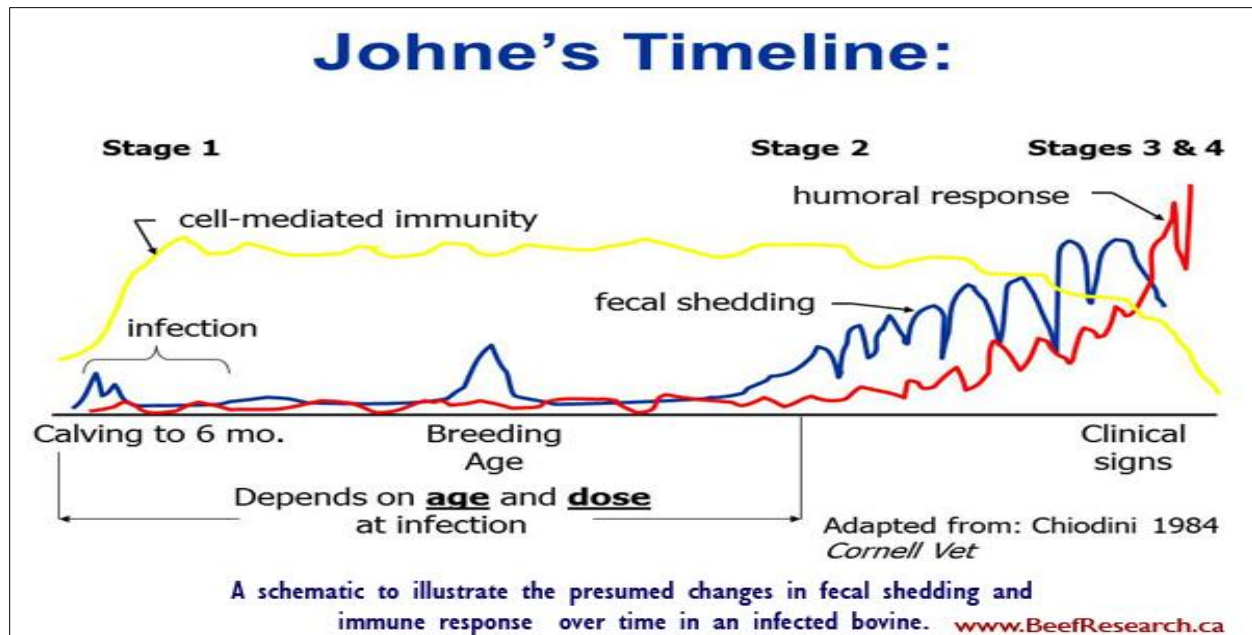


Figure 2.0.1: Stage by stage protracted timeline of a bovine infected with Johne's disease

Source: <http://www.beefresearch.ca/research-topic.cfm/johnes-disease-51>

In essence, by the time infection in the animal is identified and confirmed, the carrier animal would have had multiple opportunities to spread the disease to other vulnerable animals within the herd. Although diagnostic tests are currently available, they have proven to be less reliable and effective in detecting the presence of infected animals until they reach a stage of super shedding. Efforts to eliminate Johne's disease using “test-and-cull” methods have proven to be unsuccessful (UK House of Commons Environment, Food and Rural Affairs Committee, 2013).

JD is an endemic disease, meaning that it affects certain populations and regions (Roth 2011). As noted earlier, the number of confirmed cases of JD has been irregular. In 2005, there were 1227 cases of JD globally (Sibley and Orpin, 2016). In 2013 and 2016 there have been 5086 and 526 cases respectively (Sibley and Orpin, 2016). This variability is attributed to

inadequate surveillance. Generally adequate and effective methods of disease control adopted over the years have controlled the disease in many nations, with sporadic events which can spread and contaminate widely.

Nevertheless, JD remains endemic in the global cattle population. Over the past decade all regions of the world have reported at least one case (table 2.1). While the data suggests the disease is most prevalent and widespread in Europe, this is at least partly due to the active surveillance program undertaken there.

Table 2.1: Regional prevalence of JD (Jan. 2005 – June 2016)

Region	Confirmed cases
	JD
Africa	119
North America	604
South America	201
Asia	6,351
Europe	27,170
Oceania	3
Total	34,448
http://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/statusdetail	

There are several regional hotspots, with a mix of developing countries (both food importers and exporters) and a number of highly developed nations.

Table 2.2: Regional hotspots for JD, 2005-2016

	Country (Figures in bracket are number of confirmed cases)	
Africa	JD	South Africa (75); Libya (31); Kenya (3); Lesotho (3)
North America	JD	Mexico (583); Cuba (11)
South America	JD	Colombia (103); Ecuador (39); Chile (18); Peru (18)
Asia	JD	Japan (4,583); Korean Rep. (1,370); Iran (599); Israel (88); Palestinian (58); Thailand (58)
Europe	JD	U.K (16,099); Germany (4,583); Spain (4,122); Hungary (356); Austria (331)
Oceania	JD	New Caledonia (3)
http://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/statusdetail		

There is limited statistical and empirical evidence on true prevalence and economic losses associated with JD because of no effective diagnostic test reliably detects the infections because development is slow (Alberta Agriculture and Forestry, Livestock and Crops Division 2015; McKenna, et al. 2006). Serum ELISA and fecal culture tests are the most frequently adopted methods to detect JD, and to estimate prevalence. ELISA is rapid, low-cost (\$12/head), but low sensitivity test for Johne's disease (Dufour, et al., 2004; Bastida and Juste, 2011). Fecal culture testing offers a more specific result, but it is slower and more expensive (\$37/head) compared with ELISA. Most of the reported studies used ELISA, a few used fecal culture, and one or two used both. The United States Department of Agriculture reported in 2017 the range of options and risks of missing infected animals (table 2.3).

Table 2.3: Johne's disease testing options and the risk of buying cattle

Options	Risk
No testing.	Very risky—>5% percent chance, <u>for each purchased animal</u> of being infected with <i>M. paratuberculosis</i>
ELISA-test the individual animal before purchase; do not purchase anything from herds with cows positive by ELISA	Slightly less risky than not testing; more confidence in negative tests on older animals than heifers
Quarantine and test after purchase: ELISA + culture twice at 6-month intervals	Lowers risk and is sound policy for several infectious diseases of cattle
Partial test on herd of origin: ELISA on 30 2 nd lactation or older cows	Low risk of Johne's disease in any animal from such herds <u>but not 0%</u>
Whole-herd ELISA or fecal culture on the herd of origin.	Very low risk of Johne's disease if herd tests 100% ELISA-negative or culture-negative
Purchase only from test-negative status herds (level 2 or higher)	Lowest possible risk for purchase of <i>M. paratuberculosis</i> -infected herd replacements
https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/nvap/NVAP-Reference-Guide/Control-and-Eradication/Johnes-Disease	

Overall, the estimated JD prevalence is believed to be increasing over time (Kennedy, et al., 2016). This increasing trend of JD prevalence can be also observed from the prevalence applied in previous studies. Specifically, in the 1980s and early 1990s the lowest estimated prevalence was below 1% but rose above 5% in almost all countries after 2000. The details of prevalence estimation can be found in table 2.4.

Table 2.4: Estimated prevalence

	Study	Country	Year of study	Prevalence
Within-herd-prevalence (WHP)	Scott-Orr et al.	AUS	1988	0.1%
	Lombard et al.	US	2005	3.8%
	Raizman et al.	US	2007	8%
	Tiwari et al.	CA	2008	12.7%
	Donat et al.	Germany	2014	1.4%-54%
	Barkema et al.	CA	2015	20% ¹
	Kennedy et al.	Ireland	2016	7.4%
	Meyer and Hall	Netherlands	1994	6.2%
Sample prevalence	VanLeeuwen et al.	CA	2000	10%
	Johnson et al.	US	2001	41.8%
	O'Doherty et al.	EU	2002	7%-55%
	Mee and Richardson	Ireland	2008	3%

Source: Zhaoxue and Hall, 2017 Literature Review on Economic Impact of Johne's Disease and its Control Options in Canada working paper

Prevalence reported by existing studies in Table 2.4 is too variable to conclude any estimate of overall JD prevalence worldwide or in a specific region. Many articles have mentioned that accurate prevalence was not available, and it is difficult to estimate (Caldow and Henderson 2002; Caldow, Low, and Gunn, 2003; and Constable et al., 2017) due to limitations in diagnosis methods and the insidious nature of JD (Whittington and Sergeant, 2001; Caldow and Henderson, 2002).

Based on the 2007 Dairy NAHMS study, about 68 percent of U.S. dairy herds have at least one cow that tests positive for Johne's, with herd prevalence approaching 100% in large dairy herds (United States Department of Agriculture, 2017). There is limited evidence of incidence in Canada. Figures from 2001 indicate that 16.1% of 984 cows from New Brunswick, Nova Scotia, Prince Edward Island, and Newfoundland were found to be infected with JD (McKenna, et al., 2004.)

Bovine JD can easily be spread internationally (and probably is) because global imports and exports of dairy have been increasing, particularly in India, Australia, Brazil, New Zealand,

¹ Within herd prevalence in Western Canada and Ontario added up to 20%. Eastern Canada prevalence equaled 12%, and Quebec 5%.

Uruguay, the EU, Mexico, Argentina, the United States, and Canada (“Tuberculosis”, 2019). To this end, the industry and many governments have targeted to improve JD control.

2.2: Controlling ruminant diseases

Controlling disease means controlling the risk associated with the disease. Risk assessment has four tenants: hazard identification; hazard characterization; exposure assessment, and; risk characterization (Phillips, 2009). Hazards can be biological, chemical, and physical agents that can cause negative effects (Phillips, 2009). Hazard identification occurs when one observes a biological, chemical, or physical agent causing a negative impact (Phillips, 2009). Hazard characterization is the act of collecting data on, analyzing, and describing the relationship between the agent and the adverse response in order to determine the dosage required for specific responses (Phillips, 2009). Exposure assessment is the act of measuring what exposures are anticipated or experienced under varying conditions (Phillips, 2009). Finally, risk characterization involves assessing whether an adverse effect will occur and thresholds for impact.

The challenge is that currently JD is a non-reportable disease meaning when contamination is found, it is not a legal requirement to report it to the government. JD being non-reportable means that the disease is usually controlled by the producers. JD is only found when the bovine is wasting and showing symptoms of sickness (Cetinkaya et. al., 1997). At this point, a veterinarian is contacted, and tests are conducted to determine the cause of the symptoms. Once it is determined the disease is indeed JD, the farmer will usually cull and kill the animal and other infected animals on the farm, especially any progeny that suckled.

Internationally, there are risks associated with presenting an infected animal for export. Some countries, such as France and Germany, and some segments of the industry will test for JD. When a disease is found by importers, there is cause for alert as a disease has entered another country. The country notifies the appropriate governments of the disease.

JD is being managed by a range of approaches: doing nothing, which leads to the maximum economic loss and threats to food security; best-management practices, which often involves government regulators; cull-and-kill, which is a process that the dairy producers themselves can manage; vaccination and testing innovations, which involves vaccine producers, institutions such as universities that do research on vaccines, dairy producers, and government

regulators (as vaccines require regulatory approval); and, finally, a combination of best management practices, selected vaccination, aggressive testing, and cull-and-kill, to manage outbreaks.

There are various methods of controlling JD. One such method is test-and cull. One US study showed that this method is profitable if paratuberculosis has a higher prevalence than 5% (Collins and Morgan, 1991). While it is good health practice to cull and kill the infected herd, it is also important to note that mid-size U.S. commercial dairy farms often choose to retain cows in early infection stages to sustain milk production and farm income (Dorshorst, Collins, and Lomard, 2006). Management based practices have been shown to be a fast way to reduce JD infection rate in US dairy herds, as well as being more cost-effective (Pillars, Bolton and Grooms 2011).

Canada currently is aligned with the best management approach. The Canadian Johnes's Disease Initiative, implemented in 2013, is funded by Dairy Farmers of Canada and the Canadian Cattlemen's Association (Baker and Empringham 2013). The goal of this program is to increase awareness and educate producers and veterinarians, encourage the development and implementation of control programs in the 10 provinces, and facilitate and fund research programs on JD. One concern is that smaller and lower-budget producers were not likely to implement best JD management practices due to high cost (Kelton et al 2016). Overall, there is a lack of national urgency for a program, however there is still a voluntary JD program for reporting until funds are depleted (Baker and Empringham 2013).

Surveillance and reporting are core to disease management. The Canadian Food Inspection Agency (CFIA), the competent federal regulatory authority, and provincial veterinary authorities manage the identification of diseases. CFIA definitions of 'notifiable' or 'reportable' diseases are clearest while definitions at the provincial level can be less clear. Section 5(2) of the Canada Health of Animals Act requires any veterinarian who has any suspicion of the existence of reportable disease in Canada to immediately report such suspicion to a veterinary inspector.² Currently 31 diseases are immediately reportable in Canada, including foot and mouth disease, scrapie, trichinellosis, anthrax, Chronic Wasting Disease (CWD) and bovine TB, and a few rare indigenous diseases. A second category are those diseases that are immediately notifiable; these include mostly exotic diseases not normally found in Canada for which there are no control or

² <https://laws-lois.justice.gc.ca/eng/acts/H-3.3/page-2.html#h-4>

eradication programs. The CFIA may undertake control measures for such diseases when notified of their presence in Canada. More than 40 animal diseases are immediately notifiable in Canada. JD falls into a third category of annually notifiable diseases, which are those diseases for which Canada must submit an annual report to the World Organisation for Animal Health (OIE) indicating their presence within Canada. In general, they are diseases that are present in Canada and are of concern to our trading partners but are not classified as reportable or immediately notifiable (Government of Canada, Canadian Food Inspection Agency and Animal Health Directorate 2018).

In the current bovine trade regime, there are regulations to test imported cattle to see if they are infected with pathogens that can be transmitted to humans through consumption or handling. The current method that is employed by the majority of the border agencies responsible for testing animals, particularly cattle, is to first test a sample with the scratch-test method. If the test comes out positive (either due to detecting the disease or as a false-positive), the cattle are then culled, killed, and disposed. This results in increasing costs for sellers of the cattle, and a cost for those who pay for the disposal - the government of Canada.

Existing JD vaccines do not reduce the instances of the aforementioned costs. When vaccinated cattle are tested, they often test positive (albeit as a false positive) but are still destroyed because it is impossible to definitively determine a diseased animal cost-effectively. Any economic benefit the vaccine seller might hope to gain is jeopardized by this anomaly. Since current tests for diseases leads to false-positive of TB, producers under-vaccinate.

There are many pathways for vaccines to become commercially available. One common approach is for the creator to file for a patent and then sell the asset to other established vaccine producers. Alternatively, some developers patent and then exploit the technology through a start-up or expansion in house or through a start-up. The risks and returns vary depending on the strategy pursued.

This study is less focused on that choice and more about policy strategy, so the focus is on regulatory and politics around food security.

If standards for the regulation of vaccinations vary between trading countries, then there could be negative implications in trade, as well as high control costs for importing countries (Seitzinger, Forsythe and Madell, 1999). When regulations are not standardized, there can be information gap between trading countries. Country A utilizes system z, which is not understood

by country B, and therefore results in country B misunderstanding the vaccine used by country A, which might trigger a trade disruption.

Many international governing bodies investigate disease control, including as the World Organisation for Animal Health (OIE) (Weber-Vintzel 2010). At this point, Canada is attempting to manage JD and TB together because of their linkages. Genome Canada is investigating the possible ways to manage JD and TB using vaccination. The sciences are progressing and there appears to be an appetite for the technology but getting to a successful product launch will require navigating the regulatory system.

For the OIE to certify a diagnostic kit, which includes diagnostic assays and vaccines, it must be prove its “fitness for purpose” (World Organization for Animal Health). The applicant first submits an application form for registration of a diagnostic kit to the OIE, with the fee. The applicant is advised to coordinate with the OIE Secretariat for Registration of Diagnostic Kits (OIESRDK), which will: provide procedural guidance during the pre-submission phase; monitor regularly declarations and preliminary appraisals of compatibility of the interests declared by the individuals concerned; and, coordinate the acceptability of the application submitted. The OIESRDK may ask for additional data, clarification, or other information.

Once the information has been accepted, a chairperson, specialist, and reviewers are assigned by the OIE. A timetable is proposed for evaluation by this group. If the information provided is insufficient, the OIE informs the applicant that the application has not been accepted and a refund is issued, less 15% for administration costs incurred.

An accepted application results in the appointment of the chairperson of the review panel (CRP). These individuals are chosen from the OIE Reference Centres or from amongst other internationally renowned experts. The CRP works with the applicant to clarify all technical matters.

Once the CRP is satisfied with the information provided by the applicant, the CRP submits a final assessment report through the OIESRDK to the Members of the Special Commission. The Special Commission discusses the final assessment report and either adopts or rejects the application.

The final submission is sent to the OIE Director General, who informs the applicant of the Special Commission’s opinion. In the case of a favourable opinion, the Director General informs the applicant that the diagnostic kit will be proposed for inclusion in the register by vote

of the World Assembly of Delegates at the next General Session (this is possible at the latest 3 months before the General Session held every year in May).

At the General Session, the World Assembly of Delegates votes on a resolution for inclusion of the diagnostic kit(s) in the register. Within 14 days of the favourable vote of the World Assembly of Delegates, the OIE Register of Diagnostic Kits is updated.

Finally, mock-ups or specimens of the final outer and inner packages with labelling must be submitted to the OIE.

Overall, this is quite an extended process, so it is important to anticipate and plan the diagnostic as part of any vaccine development program.

To start that analysis, the section below discusses the current regulatory processes for introducing a new vaccine in key markets.

2.3: North American regulations

Because the US is the single largest dairy export market for Canada, it is appropriate to start with the North American regulatory system (McKenna, et al. 2004). Canada and the US are close trading partners and becoming closer because of the Canada – United States – Mexico Agreement (CUSMA), which will allow for more dairy products to be imported into the hitherto subsidized Canadian market (Foreign Affairs Trade and Development Canada, Information Technology, & Corporate Procurement 2018). A new vaccine could be particularly useful as all three countries have endemic JD; a vaccine would yield significant benefits in Canada, the United States and Mexico as Johne's disease is prevalent throughout the region. A recent outbreak in Alberta highlights the risk of not acting proactively to manage any disease (Bell, 2018).

In Canada the Health of Animals Act and Regulations governs the regulation of veterinary biologics in Canada, which authorizes the Minister of Agriculture and Agri-Food to regulate the manufacturing, importation and sale of animal vaccines. The Canadian Centre for Veterinary Biologics (CCVB) of the Terrestrial Animal Health Division, Animal Health Directorate, and the Canadian Food Inspection Agency have been delegated with regulating the testing, importation, and distribution and sale of vaccines. It will be important to consult and liaise with these organizations when thinking about producing vaccines for animals. These organizations review, approve, and inspect facilities related to the production of vaccinations to

be used and sold in Canada, and exportation of these vaccines. The licensing requirements are described in the regulations and in guidelines, which are available from the Canadian Centre for Veterinary Biologics.³

Globally, vaccines are evaluated on a case-by-case basis and are licensed based on fulfilment of four criteria: purity, potency, safety and efficacy. While efficacy shows the protective effect (immunogenicity) of a vaccine, potency is demonstrated by having each batch of the vaccine produced provide the same level of protection as the original vaccine (Draayer, 2011). The onus to prove that these requirements are met is on the manufacturer. “A risk-based approach is used to evaluate the safety of the product in target and non-target species, humans and the environment. Other federal departments, such as Health Canada or the Department of Fisheries and Oceans are consulted during the risk and environmental assessments, when human health issues or national fish health concerns are involved. In many respects, the Canadian licensing requirements are like the United States Department of Agriculture requirements for veterinary biologics. Documents prepared by using the United States Code of Federal Regulations (9 CFR) protocols and test procedures or equivalent are accepted by the CCVB for review and licensing purposes.

Manufacturers and researchers intending to license experimental vaccines are encouraged to consult with the CCVB early in the product development process, so that the research data and quality assurance documentation are consistent with Canadian regulatory requirements, as specified in the Health of Animals Act and Regulations.

In addition to conforming to the Health of Animals Act and Regulations, all research and development projects must meet the standards and requirements for laboratory biosafety and animal care described in the current edition of the Health Canada Laboratory Biosafety Guidelines, and the Canadian Council on Animal Care Guide to the Care and Use of Experimental Animals.

Recently, regulations have been implemented to recover fees for some of the veterinary biologics regulatory services including issuance of permits, licenses and inspection of facilities. The cost recovery schedule for veterinary biologics is outlined in the Health of Animals Act and Regulations and the Canadian Food Inspection Agency Fees Notice, Part 11 - Services Related to

³ <http://www.inspection.gc.ca/animals/veterinary-biologics/guidelines-forms/4-5e/eng/1318508906578/1318509047147>

Veterinary Biologics (Items 40-50). Service standards (response times) have been established for these regulatory services and are available from CCVB.”

The United States’ vaccine regulations are like Canada’s in the sense that there is much regulatory forethought, as well as a significant role for the private market. In the United States, regulation of vaccines for dairy herds is established and implemented by the United States Department of Agriculture (USDA). The USDA creates regulations on a case-by-case basis, which is a process that may take 6 years or longer (Smyth, McDonald, Falck-Zepeda, 2014).

The United States is a large market to access for vaccination products. On average, the US produces 19,932 lbs of milk per cow in its lifetime (The United States Department of Agriculture, 2016). In the United States, newly acquired small herds (30-99 cows) had an overall testing rate of 74%, while medium sized herds (100-499 cows) has a testing rate of around 42%, and large herds (500 plus) had a testing rate of 50% (Ochieng, and Hobbs, 2016). The USDA utilizes the internet to disseminate information to increase participation by ensuring that these producers have access to internet services. The issue with JD control in the United States is that veterinary services are not always available in proximity to where livestock operations are located (Ochieng, and Hobbs, 2016).

Understanding that the vaccine induced antibody interferes with serologic surveillance and epidemiology of Johne’s-disease-infected animals has led to a policy of utilizing the Differentiating Infection in Vaccinated Animals (DIVA) tests that are sensitive to the markers caused by vaccines (Lee, Senne, and Suarez, 2004). Utilizing this method of DIVA allows for economic loss to be contained, as well as better management of the risk of spreading the disease. DIVA can also be seen as a quality control mechanism as it ensures that infected animals do not pass through the borders.

2.4: International Regulatory Framework for Animal Disease Control and Use of Vaccines

To control diseases, producers of vaccines and the like need national approval and international recognition. The World Organisation for Animal Health (OIE) provides regulations concerning animal vaccines, vaccination and other measures aimed at reducing the risks associated with animal diseases (Garland, and de Clercq, 2011). Although international standards have led to marked decreases in risk of contamination and spread of disease, there is no way to

attain zero risk, and therefore, minimizing risk is the best policy makers can hope to achieve through the methods described in this study.

Bilateral agreements between nations allow for information on the validity of risk of new technology to flow in real time, which should improve confidence levels of both importing and exporting countries (Sutmoller, and Olascoaga, 2013). While the bilateral, multilateral, and trilateral trade agreements are important, the OIE and expert committees of the importing and exporting nations are key to gaining market confidence in new technologies (Garland, and de Clercq, 2011). Core to this is a need for transparent documentation of the animal health situation, including factors required to assess the risks involved (Garland, and de Clercq, 2011).

OIE animal health standards are implemented to facilitate relatively risk-free and safe trade in livestock and livestock products. Listed in these standards are transboundary animal diseases that are at risk of being transported from one trading partner to another. These standards draw on the norms of international trade and negotiations (Thomson et al., 2004; Milstien, Kaddar and Kieny 2006). One such standard imparted by the OIE is to remove regularly-infected parts of bovines, such as the bones and lymph nodes, for safety purposes. This is something that has been normalized internationally. However, when risk mitigation strategies are difficult or impossible (e.g. when infected animal parts are not removable), then vaccines, vaccine marker tests like DIVA and enzyme-linked immunosorbent assays (ELISA), and sound facility management in the supply chain are needed to safeguard against transboundary movement of disease and any related disruption. Such DIVA control strategies were utilized to control avian influenza infections in poultry (Capua, Terregino, Cattoli, Mutinelli, Rodriquez, 2002).

Other nation states, such as the European Union, are important. In the United Kingdom, studies have shown that ELISA tests used to detect antibodies to differentiate vaccinated from infected animals has led to positive economic impacts by allowing for trade to remain open (Mackay, et al. 1998). If there was no system implemented to differentiate between vaccinated and infected animals, country or regional-level restrictions would jeopardize free trade. With the differentiation, international barriers to trade and externalities stemming from new vaccines are kept at a minimum.

Specifically related to JD, the United Kingdom has implemented a National Johnne's Disease Management Plan, which aims to have at least 80% dairy farmers enrolled (UK House of Commons Environment, Food and Rural Affairs Committee, 2013). This goal is anticipated to

be reached due to the recruitment of the 23 milk purchasers' organizations, large dairy herds, and registration of new companies. However, the success of control programs varies depending on eagerness to implement robust controls, especially at the farm level (Sibley and Orpin, 2016).

Canadian dairy products have not typically been exported to the UK (Government of Canada Canadian Dairy Information Centre 2018). Instead the UK is a competitor to Canada as they export to countries we export to, such as the Philippines (Government of Canada Canadian Dairy Information Centre 2018). If the UK were to lower the levels of false-positives, their exports would likely grow at the expense of Canadian dairy exports.

Meanwhile, France has farmer organizations, called *Groupeement De Defense Sanitaire* (GDS), that support farmers in controlling animal diseases, with specific actions on John's Disease. France also utilizes a National Control Plan implemented in 2000 to run fecal diagnostic tests on herds, followed by individual tests, early culling, and incentives for testing (Liu et al., 2003). Although only 3% of herds are enrolled in this program, it is the complementary National Certification Program established in 2002 that runs ELISA tests as part of regional herd screening that makes France able to respond to JD. Information on the dangers of not testing and incentives are offered to farmers (Garrido et al., 2013).

Germany's federal legislature regulates infectious diseases through the veterinary authority; however, JD is a low priority. The National reference lab licenses tests and publishes an official manual of approved tests and specialist counselling for veterinary authorities at the regional level. In 2014 the Ministry of Food and Agriculture recommended national hygiene implementation for ruminants, though only seven states in Germany used these recommendations (Weber-Vintzel, 2010). The process recommended to first sample the environment semi-annually, followed by annual serological testing and removal of sero-positive animals, and finally, annual bacteriological testing and removal of the positive test cases. Although Germany is a member of the European Union, it has little insight in implementing European Union legislature (Kelton et al, 2016), perhaps because the highest within-herd prevalence of JD, in the state of Thuringia, is only 9.6% (Donat et al., 2014). Canada exports very few dairy products to Germany (Agriculture and Agri-Food Canada 2018) and is neither an importer nor competitor in third markets.

Countries, producers of vaccines and dairy, the public, and various non-profit organizations have a stake in preserving food security. There have been many improvements to

regulatory practices following the innovation of vaccines; however, vaccines alone do not curb risk in transmittable diseases. In addition to vaccine implementation, disease surveillance, biosecurity at the farm level, traceability and control of the source cattle and slaughterhouse inspections are quintessential to risk management (Garland and de Clercq, 2011).

The diversity of approaches, and the fact that food security is a shared problem, make the common pool goods theory particularly useful. The theory of common pool goods is discussed next.

Section 3:

Conceptual Framework

The feasibility of potential policy options is considered in this section. This method will illuminate each institution's ability to implement changes and develop policy. At root, the challenge is to know the nature of the goods that will be delivered through a range of strategies and the incentives or disincentives that will affect their provision. This will help to unpack the intricacies of this problem and to determine which actors in this complicated space may be able to effect meaningful change that reduces the incidence of JD and false positives triggering TB and helps to obtain global food security.

I apply the theories from Ostrom's common pool good and Institutional Analysis and Development Framework theories, which have historically been applied to water allocation rights (2005, 2006), and Mahoney's vertical contracting, which has historically been applied to economic transaction costs (1992). This thesis uses these theories in a different manner to explain the possible solutions to JD false-positives, disease management, and food security.

3.1: Feasibility

Changing the testing and vaccination regime in a country is a public policy issue. Public policy issues can only be implemented if they are feasible. The feasibility of the political landscape is an important part of the discussion of a change in practices within any regime.

According to Majone (1975, pp 259) political feasibility can be considered as "the limitation of the available political resources; those relating to the permissible distribution of the benefits and costs of policy (distributional constraints); and those imposed by the institutional framework."

First, the policy to be implemented cannot be exclusionary and disproportionate – that is to say, the cost should not rest solely on one actor to deliver best management regimes or disease control. If the costs rest solely on the producers, there could be endless litigation, or they might simply refuse to adopt the approach; ultimately such a solution would be ineffective (Majone

1975). Therefore, it is essential to find a solution that has costs fairly distributed among all actors involved.

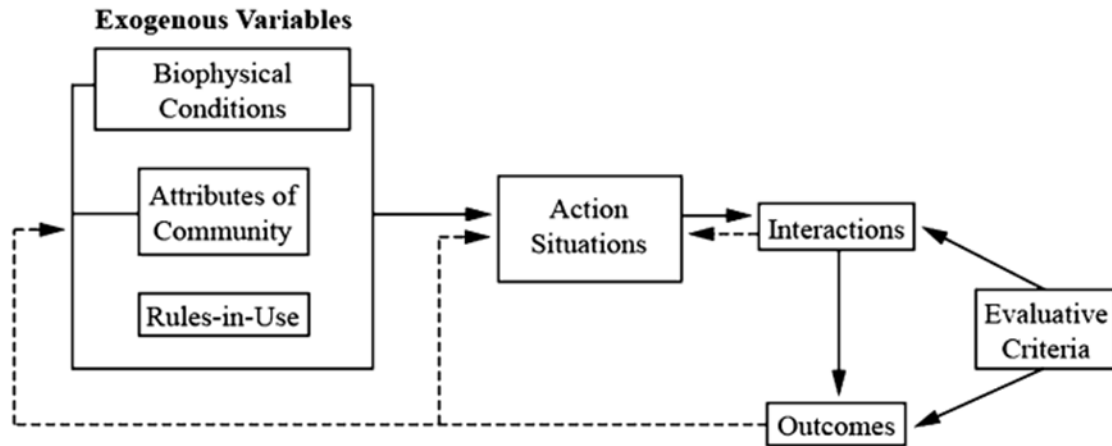
Secondly, for a policy to be politically feasible, the institutions involved and motivated by the solution must be capable of implementing the necessary changes. Policy makers are the cornerstone of most systems and hold much power, usually being able to decide categorically whether a policy change is adopted or considered (Majone, 1975). Institutions, however, also need to be equipped to implement decisions; this requires appropriate power, capacity and access to appropriate resources. These resources include time, finances, and the free-will to explore additional options.

Success of a program relies on many connections between various actors and institutions. When any new strategy is proposed, there is usually a gap between the intent of policy makers and the interests of end users. In the context of animal diseases, it is up to the producers to ensure there is communication between the government, policy makers, and consumers that will allow for the successful implementation of a new safety strategy. This institutional constraint points in the direction of the Institutional Analysis and Development Framework as a way to unpack the decision and implementation spaces that will need to function to deliver better policy outcomes.

3.2: Institutional Analysis and Development (IAD) Framework

Examining the institutions and analyzing their ability to provide solutions to common pool good problems is best accomplished with some conceptual structure. Ostrom's institutional analysis and development (IAD) framework offers an accessible and tested analytical tool (Ostrom, 2005). The IAD framework offers a conventional input-activity-output framing, focusing on actors, institutions and problems. At its most basic level, the IAD framework consists of three elements: 1) exogenous variables; 2) an action arena; and 3) the interactions that generate outputs and outcomes (Ostrom, 2005). Ostrom defines exogenous variables to include biophysical or material conditions (e.g. the physical and biological constraints and challenges in different growing regions), attributes of community (e.g. the industrial structure and political systems governing agriculture) and rules (e.g. the overarching legal and institutional norms and practices that delimit choices) (2005). The action arena is composed of action situations and participants – variously defining problems, issues, policy areas and networks or communities of individuals and organisations.

Figure 3.1: Components of the IAD Framework



Source: Ostrom 2005, pp. 15.

In this case, the outcomes are a range of strategies for managing the risk of JD, including the cull and kill method, vaccination with improved diagnostics, and a range of regulatory responses. Each of these choices would entail a different risk profile for the market and consumers, such that the outputs would be a conceptually differentiated set of attributes. This opens an opportunity to help frame the strategies in the context of a typology of goods in food markets.

3.3: Common Pool Goods from regulatory processes

There are a range of goods defined by theory. One configuration is the classical search-experience-credence framing, where consumers can know everything they need to know for search goods, but can only fully appreciate an experience good by consuming the product and may never independently determine the full array of benefits of a credence good, as many of its impacts may be subtle and only determined over a long period. All search and many experience goods can be delivered efficiently through the marketplace as private goods, but markets fail to produce the optimal amounts of some experience goods and all credence goods. Food borne disease converts animals and meat, which otherwise might be search or experience goods, into credence goods. Different market structures are needed to more effectively manage products

with these attributes. Some health measures are pure public goods, in that everyone benefits equally, but JD is more localized in the parts of the global food system and affects different consumers differently, which makes it more of a common-pool type of good.

The definition of a common pool good is any good that is a shared resource between a group of people (Hess and Ostrom, 2006). Maintaining food security is a concern for the broader public, but the interests and benefits are not universally distributed, making both pure public provision or pure private market less effective mechanisms for delivery. Governments have different interests based on whether they are governing food exporting or importing countries, the global supply chain is differentially affected by disease and has widely different capacity to manage disease when it emerges, and consumers have differential interests, depending on their diets.

In the context of JD management, there are four main actors: vaccine developers and manufacturers who seek to gain from the production and sale of vaccines; the general public that seeks safe, nutritious and affordable food; dairy farmers who manage the herds where infection would occur, incur many of the costs of lost production and will have to pay for many of the remedies to manage JD; and governments because they have a broader set of objectives, including food safety and security, industrial competitiveness and international market access.

Table 3.1 illustrates the differences between the various goods, based on the degree of excludability and rivalry. Excludability is defined by whether others can be excluded from the benefits of a good. For example, your household furniture is perfectly excludable, as long as you lock your doors to others, while clean air is shared by all. Rivalry is defined as the impact of others consumption on your benefits: shoes are perfectly rival, in that only one person can wear a pair at any time, while public health (as in the freedom from infectious disease) benefits everyone equally. The state is the only effective agent for delivering pure public goods (those that are non-rival and non-excludable) and markets are the most efficient and effective means of delivering private or market goods (those that are rival and perfectly excludable), but many goods fall in the middle, with a range of non-state, non-market solutions available. Public goods are goods such as knowledge since there is no way to exclude individuals from knowledge and having one person have the knowledge will have no bearing on the amount of knowledge available to another individual. Purely private goods, such as clothes and pens, are goods that will be excludable from others and utility is subtracted from the total units available to others

when that good is used. Toll or club goods involve goods that exhibit low rivalry but are excludable, can be produced: day-cares or country clubs are examples.

The problem of managing animal diseases, like JD, is best categorized in the common pool good category because if the herd is vaccinated with the appropriate vaccine, that herd is excluded from infection, but may cause market disruptions if the vaccinated animals are presented for trade and testing delivers false-positives. The vaccinated herd is also subtracted from the total number of infected animals. The infected herd, in contrast, is also totally subtracted from the total pool of tradable goods. Although this is not a perfect fit, it is the closest that can be hypothesized.

Table 3.1 Types of Goods

		Rivalry	
Excludability		Low	High
	Difficult	Public Goods	Common-pool resources
	Easy	Toll/Club Goods	Private Goods

Mahoney (1992) posits that different organizational structures operate depending on the nature of a good. When assessing the risk of a product and the assignment of property rights to the good, which are regulated both by government bodies and market functions, simply utilizing property ownership and negotiation tactics to assign responsibility is often an inadequate policy option. Mahoney (1992) asserts that vertical contracting, whereby a commodity has actors ranging from producers to government bodies contractually linked, may be necessary when market agents fail to negotiate effective contracts that manage the costs and benefits of each exchange. In the case of management of JD, markets are unable to successfully negotiate fully delimited contracts to appropriately assign the costs and benefits in ways that reduces or eliminates JD. Governments have tried and failed to implement JD control programs to eradicate the disease, suggesting Mahoney's theorized vertical contracting is not enough to align risk and returns among governments, market agents, and non-governmental organizations to eradicate the public and private good problem of bovine JD.

Internationally, regulators have assessed risks by identifying hazards associated with agents that relate to the commodity. To reduce risk of contamination, producer-specific practices

are necessary, but often need to be supplemented with other strategies. In the case of foot-and-mouth disease, good management practices, such as deboning, maturation, and cleaning mechanical processing equipment (Garland and de Clercq, 2011) are used to mitigate the spread of carrier viruses. Canada has some experience with an E. coli vaccine. Market incentives highly influenced the producers' willingness to adopt control measures. In this case, governments and the markets targeted adoption to those producers more at risk of disease, on the assumption that the highest benefits would flow from targeting those most needing to control the disease. The conclusion was that a one-size-fits-all approach will yield little benefits in both commercial and public safety aspects (Ochieng and Hobbs, 2016).

There are many voices and interests in each type of good. Common pool goods have many interested parties. When organizations and operational models are working collaboratively, these actors must also work together. The overall objective for the next section is to unpack the type of goods involved in vaccine management for JD and TB and investigate the institutional capacity to manage and deliver those goods.

To conclude, exploring the options requires a focus on: the cost of the solution and benefits and their distribution among the actors involved; the institutions in place and their ability to adequately investigate and implement solutions; and the nature of the goods involved. The following section unpacks a range of scenarios for delivering and management of JD.

Section 4:

Scenarios

As it stands, there are many options open to decision makers attempting to control JD. The standard baseline strategy is test-and-cull. This method has been found to be profitable in the US if paratuberculosis has a higher prevalence than 5% (Collins and Morgan, 1991). While it is good health practice to cull and kill the infected herd, it is also important to note that mid-size U.S. commercial dairy farms often choose to retain cows in early infection stages to increase farm income (Dorshorst, Collins, and Lomard, 2006). Clearly cull-and-kill is a suboptimal strategy if one seeks to control JD.

Given that JD is not an immediately-reportable disease, a range of alternative or additional strategies may be needed to get to the root of the endemic infection rate, including: best-management practices, which would involve government regulators; cull-and-kill, which is a process that the dairy producers themselves can manage; vaccination and testing innovations, which vaccine producers, institutions such as universities that research on vaccines, dairy producers, and government regulators (as vaccines require regulatory approval); and, finally, a combination of best management practices, selected vaccination, aggressive testing, and cull-and-kill, to manage outbreaks.

Scenario 1: The status quo of cull-and-kill

The cull and kill method involves separation of the infected heifer, calf, or cow from the other livestock, and transportation to a killing facility for the livestock to be disposed. Infection is detected through two methods: testing of animals and understanding the visible signs of JD, which include wasting, diarrhea, and shedding (Donat et al., 2014). Culling and killing relies on farmers, governments, and slaughter houses all doing the right thing at the right time. Table 4.1 illustrates the differential benefits and costs of relying on the cull and kill method.

Table 4.1 Scenario 1: Cull and kill strategy

Actors	Benefits	Costs
Dairy Producers	<ul style="list-style-type: none"> • No future production loss • Compensation for destroyed animals (\$10,000 for registered cattle, \$4,500 for non-registered cattle)⁴ 	<ul style="list-style-type: none"> • Loss of animals • Loss in revenue and profit • Possible loss of trust from the public
Government	Control of JD	<ul style="list-style-type: none"> • Economic losses associated with government sanctioned clean-up for bio-hazard removal • Cost of disease containment in the event of an outbreak • Economic losses associated with reduced trade due to being blacklisted for having infected herds • Cost of paying compensation for destroyed animals (\$10,000 for registered cattle, \$4,500 for non-registered cattle)⁵
Vaccine producers	N/A	<ul style="list-style-type: none"> • Forgone production
Public	N/A	<ul style="list-style-type: none"> • Small price increases due to quantity reductions • Higher taxes or few services due to public costs associated with government sanctioned clean-up for bio-hazard removal

It is important to note which institutions are utilized for each scenario. Four institutions regulate and implement policies of each scenario. The actors of this scenario are as follows: dairy

⁴ <https://laws-lois.justice.gc.ca/eng/regulations/SOR-2000-233/page-2.html>

⁵ <https://laws-lois.justice.gc.ca/eng/regulations/SOR-2000-233/page-2.html>

producers, the government, vaccine producers, and the general public. The role of the actors, respectively, is to: produce milk; regulate the good and protect the public; produce (or in this case forgo producing) a vaccine; and consume the milk produced. In effect, this scenario is the status quo, where the distribution of costs and benefits are accepted (sometimes grudgingly) but effectively set the baseline for assessing the other scenarios.

In this scenario, dairy producers, or the market, is self-regulating. There are no other institutions in play when it comes to cull and kill other than the institutions responsible for detection and clean-up. In the first instance, dairy farmers incur significant costs for their part in the system. When cows present with symptoms of JD then the entire herd at the farm may be quarantined, and a thorough fecal culture test can be done to see if any other animals are infected. The infected cows are then culled and transported to an abattoir for disposal to reduce spread of the disease. Farmers incur transportation costs to send the cows to slaughter, which increases the economic loss associated with the infected cow. The farm is then cleansed as thoroughly as is possible. Each of these steps imposes significant costs on producers, which explains why many may ignore endemic infection. When cull and kill is the go-to strategy of disease management, there may also be restrictions on the flow of animals and milk products from infected herds, as those farms are no longer reputable sources of safe products. Farmers and producers have little to gain when cull and kill strategies are implemented as their herd size is reduced due to the culling of their livestock other than potentially eliminating future production losses. When the government knows that a specific disease is found in a certain farm the government will quarantine the farm. Due to this quarantine, there is a loss in revenue. In all, farmers see cull-and-kill as a necessary but far from a sufficient or satisfactory strategy.

Government costs associated with cull-and-kill strategies of disease management vary. When a disease is found, governments will need to impose quarantines to ensure there is no disease outbreak to surrounding farms or wildlife, which creates an additional cost to the government. The benefits governments can hope for are that the disease is adequately contained. Containment, however, only occurs if there is a rapid response and swift implementation of quarantine, which is often not feasible in rural areas where it can take hours or days to get to and quarantine a suspected infected farm. This method holds little benefit other than the fact that the status quo is maintained which limit costs. The system is adequate, so that there is little interest in government changing the status quo. The only time when government attention is focused is

when the international market determines that animals are infected and disrupts trade flow. If producers are unable to supply dairy internationally or locally, then economies are negatively impacted and governments respond. A recent salient example in Canada was the detection of a few bovine spongiform encephalopathy (BSE) cases in 2003-5, which led to significant market disruption and a sustained and aggressive public response with detection, research and management (Stephenson 2013).

The vaccine and animal health industry are largely not engaged in this scenario. Veterinarians are part of the surveillance system, but apart from isolation and cull orders, they have little to offer. While there are no other explicit costs, there is the opportunity cost of forgone revenue to vaccine developers and manufacturers. As with most public policy, however, those facing opportunity costs resulting from foregone market opportunities are highly unlikely to be engaged in the policy conversation—we will see in other scenarios that these firms will have more to contribute to the policy conversation.

The public ultimately bears much of the cost when cull and kill management practices are implemented, either directly or indirectly as citizens and taxpayers. In this scenario, there is a modest increase in prices for consumers as supply is reduced, both due to the continuing endemic impacts of the disease and the culling of producing animals, and the farmer cost of culling that are passed on through the price of milk. The benefits of the cull and kill strategy for the public is that the disease will remain contained, albeit not eradicated.

Scenario 2: Renewed management practices

Best management practices involve a working understanding of the biology of JD that allows producers to integrate JD control measures into management routines (Rossiter and Burhans 1996). Capital investments, increased attention to cattle health, and more labour force training would all be required to improve JD control (Rossiter and Burhans 1996). Best management practices involve things such as erecting new facilities to separate young calf from mature cows. By separating calves from mature cows, fecal matter, which is a primary vector for transmission, would not be ingested by calves. The separation can be accomplished by simply moving infected animals to separate sections of the farm (Rossiter and Burhans 1996). Farmers can also manage herds by ensuring calves are not at grass where mature cows were at grass (Cetinkaya et al., 1997). Winter housing length and types also factor into best management

practices (Cetinkaya et al., 1997). If a calf is housed in a facility that also has mature cows, then there is possibility of contamination. Erecting separate facilities aids in this process but is a capital investment not every farm can make.

Table 4.2: Scenario 2: Best management practices

Actors	Benefits	Costs
Dairy Producers	<ul style="list-style-type: none"> • Better disease management and higher productivity 	<ul style="list-style-type: none"> • Cost of new facilities • Small herd size farms are unable to feasibly implement practices • Public trust could be lost if disease is found on premises • Unable to trade to exporting countries if infections found
Governments	<ul style="list-style-type: none"> • Better control of JD 	<ul style="list-style-type: none"> • Increased money spent on control, evaluation, and man power for inspections • Loss of public trust and market disruption if best management practices are not implemented and/or enforced
Vaccine Producers	<ul style="list-style-type: none"> • N/A 	<ul style="list-style-type: none"> • Foregone profits
Public	<ul style="list-style-type: none"> • Lower prices due to higher productivity and less market disruption 	<ul style="list-style-type: none"> • Higher taxes or lower services due to ongoing costs and market disruptions

This scenario mobilizes two main actors: government which works with the industry to develop and promote best-management practices, and the dairy farmers who implement the best-management practices.

The benefits of best management practices for producers are that they are able to mitigate disease. Control of disease will allow for producer's reputations to remain intact when trading products. Moreover, there is a benefit of not needing to test the entire herd if an infection is found. Dairy producers would have more costs associated with implementing best management practices such as building new facilities to separate infected or older cows from uninfected or young calves, especially for farms with small herds. The other cost associated with best management facilities is having additional labour to look after and manage calves and cows that are infected. Pillars, Bolton and Grooms (2011) concluded that better management practices were a fast and cost-effective way for domestic producers to reduce JD infection rate in US dairy herds.

Compared with the status quo farmers face lower risks of infections but Rossiter and Burhans (1996) assert that where trading countries do not vaccinate, there is a higher cost to all actors involved (except the vaccine producers who are not involved in management of this disease). One challenge is that best management practices are not overly effective for farms with small herds. Since herd sizes in Canada vary, it can get costly for SMEs (Kelton et al, 2016). SMEs may not adhere to best-management practices resulting in losses associated with infection, which negatively affects the industry and market. Moreover, as some producers may not be keen on spending the money for the new facilities the government might need to step in to manage the risk, which would create a cost for governments. The high entry costs for smaller producers could be off-set by introducing government subsidies but this would lead to higher costs to governments and in turn to the public as taxpayers.

Governments benefit from best management practices by having controlled JD and TB with costs being borne by producers. This results in enhanced international trading abilities, and more movement of animals and their products across borders. Governments do not have many costs associated with best management practices. It is the responsibility of the producer to follow practices that would reduce infection rates, largely in response to the economic incentive. There are only costs if governments choose to ensure compliance of best management practices. Ensuring compliance also means regulatory implementation, and harmonization across producers within a given territory or among trading partner countries.

Vaccine producers do not have benefits from this scenario as they are not active in the situation. While vaccine producers would face an opportunity cost that would be unlikely to motivate them to engage.

The cost to the public if best management practices are implemented at the farm level depends on whether or not the government chooses to monitor and regulate best management practices. If governments do want to regulate the practices, then the programs implemented for monitoring will be a cost to the public. Otherwise, there are few other costs to the public except for the fact that best management practices alone do not fully control JD, which means that infection is still likely to occur. If infection does occur, then there are economic losses. The public receives benefits from having the diseases controlled. Additionally, they also receive benefits when economic activity is not hampered by infection; a stronger economy leads to better opportunities for the entire region.

While best management practices would generate some improvements over the status quo, the distribution of costs and benefits is such that alone it will not fully address the risk of outbreaks of JD infection and hence would offer only a modest improvement for the marketplace.

Scenario 3: Vaccination without new diagnostics

Vaccination is the administration of antigenic material (a vaccine) to stimulate an individual's immune system to develop adaptive immunity to a pathogen (Gutierrez, Spero, Ga, Mirko, De Groot, 2012). Vaccines can prevent or ameliorate infectious disease. Vaccination is used for both humans and animals. Vaccines have been regarded as a safe, effective, and cheap option to prevent diseases. If many animals in a population are vaccinated, then herd immunity can be realized; some assert vaccination above 80-95% are needed to realize herd immunity, depending on the infectiousness of the disease.

Vaccines have been used for JD since the early 1990s (Bannantine and Talaat, 2015). Live attenuated vaccine strains are currently the industry standard (Bannantine and Talaat, 2015). The Dutch attempted to utilize killed vaccines to reduce disease. Table 4.3 shows a range of vaccines for JD currently in the market. There are no vaccines yet being used in Canada for JD as they cause false-positives for TB (Johne's Disease, 2018).

Table 4.3: Recent JD vaccines

Company	Type	Source	Adjuvant	Species/Country
AquaVax	Live	316F	Saline	sheep (NZ)
Fort Dodge (Mycopar)	Killed	M.a.a. strain 18	Oil	cattle, sheep (US)
Fromm Labs, US	Killed	M.a.a. strain 18	Oil	cattle, goats (US)
Fromm Labs, US	Live	316F	POP	Cattle
Merial (Neoparasec)	Live	316F	Oil	cattle (Germany); sheep (Spain, NZ); goats (France)
Ovejero (Lio-Johne)	Live	316F	Oil	sheep (Spain)
Phylaxia	Killed	5889 Bergey	Oil	cattle (Hungary)
Weybridge UK	Live	316F	POP	cattle, sheep (UK)
Zoetis (Gudair)	Killed	316F	oil	sheep (Aus, NZ) goats (India, Spain)
Zoetis (Silirum)	Killed	316F	oil	cattle (Spain, Aus, USA) goats (Spain)

Note: POP = paraffin, olive oil, pumice stone powder. Source: Bannantine and Talaat (2015).

Preventing the spread of JD has been demonstrated to be possible through vaccination (Bannantine and Talaat 2015). If an animal is vaccinated, then the immune system of the animal will attack the virus. Once herd immunity is realized (probably at ranges of 80-95% of all animals due to the infectious nature of JD), then there will be a chance to eradicate or at least remove the disease from the list of endemic agents. The major problem with traditional vaccination of JD is that the resulting antibodies have been found to trigger false-positives in TB tests, as mentioned earlier. Moreover, some farmers were found to neglect other management practices when using vaccines; vaccines tend to be viewed as the only necessary practice to implement to control for JD (McKenna et al. 2006; Schaik et al 1996).

Table 4.4 illustrates the differential benefits and costs of introducing a new vaccine, albeit without a corresponding diagnostic test to enable regulators and the market to differentiate between JD vaccinated animals and TB infected animals.

Table 4.4: Scenario 3: Vaccination strategies

Actors	Benefits	Cost
Dairy Producers	<ul style="list-style-type: none"> • Reduced infection rates and higher milk productivity • Reduced cull and kill, therefore less loss of animals • Public and market trust may be strengthened 	<ul style="list-style-type: none"> • Costs of vaccines • False positives may still arise leading to continuing cull and loss of animals
Governments	<ul style="list-style-type: none"> • Prevent disease from spreading • Generate consumer and citizen confidence 	<ul style="list-style-type: none"> • Incentives/educational materials generate costs
Vaccine Producers	<ul style="list-style-type: none"> • Profits from sale of vaccines • Advanced research and development as competitive advantage 	<ul style="list-style-type: none"> • R & D and commercialization costs
Public	<ul style="list-style-type: none"> • Reduction in market disruption and greater confidence in food safety and security • Lower risk of catastrophic market disruption that would generate taxes 	<ul style="list-style-type: none"> • Some potential increase in milk prices as higher costs passed along • Some continuing public costs of implementation that are passed along through higher taxes or lower services

In this scenario, there is no use of synchronized testing between trading partners. Actors in this scenario are the same as the first scenario, but we have more institutions interacting in new ways. Dairy producers still self-regulate as they decide when to implement vaccinations, but other players and actors are now more actively engaged.

The costs are still disproportionately distributed. Farmers once again are the center of the story. Assuming an efficacious vaccine can be developed and navigate the regulatory system, farmers will ultimately determine if and how it gets used. Evidence suggests farmers receive

benefits in many ways by vaccinating. Firstly, cull and kill usage is reduced since vaccinating provides safety from disease spread, which results in less lost income associated with cull and kill methods. More directly, farmers that implement vaccines will have stable income, production, and trading capabilities. Ugochukwu and Phillips (forthcoming) undertook a survey that revealed that 32% of beef farmers and 35% of dairy producers are willing to pay an average of CAN\$7.50/animal/year for a JD vaccine. On the extremes, 14% of dairy farmers and about 6% of beef farmers are willing to pay more than CAN\$20/animal/year for JD vaccine, while more than 20% of the farmers are not willing to spend more than CAN\$5 for a new JD vaccine per animal per annum in their operations. So, there may be a sweet spot that would entice farmers to vaccinate.

Table 4.5: Farmer's willingness to pay for vaccine by price

\$/year/animal	Beef	%	Dairy	%
< 5	55	42.6	28	22.5
5 – 10	41	31.8	43	34.5
11 – 20	25	19.4	36	29.0
>20	8	6.2	17	14.0
Total	129	100.0	125	100.0

Source: Ugochukwu and Phillips (2018).

Nevertheless, false positives may still occur, affecting dairy producers negatively, which would cause losses of income, product, and future trade. Additionally, farmers would likely have to spend more time on implementing vaccines as a management practice. Some smaller farms may not have the necessary resources to vaccinate all animals, and sometimes there may be educational shortcomings effecting the proper implementation of vaccines. Compared to the cull-and-kill strategy, the likelihood of contaminated animals disrupting international trade would be down, but the risk of false-positives disrupting trade remains high. Market disruptions are the highest cost variable – the Canadian Cattlemen's Association estimated the BSE crisis of 2003-5 cost the industry an estimated CDN\$6-10 billion (Stephenson 2013).

Governments would have a new array of benefits and costs associated with this strategy. Governments receive benefits in the form of disease control. When vaccines are implemented, the governments and the public they represent are protected. If disease is mitigated then economies thrive, and production can continue to benefit the country. On the expense side, there may be need to assist farmers to effectively use vaccines. Without adequate education, there is a risk they may neglect other management practices that protect their farm from other threats. If farmers neglect other best management practices, such as testing and separation of calves from mature cows, then there is a chance that other diseases or threats impact the economy negatively (Alberta Agriculture and Forestry, Livestock and Crops Division 2015). Similarly, the government would be the backstop for the industry if false-positives occur when JD is vaccinated using traditional vaccinations. The initial government response to the BSE crisis in Canada in 2003-5 was an offer of CDN\$300 million to support the clean-up and to support the market, so this can be a significant cost depending on the degree of market disruption.

This is no net cost to vaccine producers in this scenario. A viable product in the market would only occur if the revenues exceed the variable cost. There is always the risk that the cost of research and development may not be fully recouped. Overall, one would a priori assume that vaccine producers would be motivated by this opportunity and more engaged in the policy discussion than under the status quo.

As in the status quo case, consumers are the ultimate payer. When false-positives occur, the economy is negatively affected. If vaccination for JD triggers TB false-positives, the costs of quarantine and market disruption would raise costs to taxpayers, while at the same time probably raising the cost of milk for consumers. This is what makes effective control most attractive. Effective disease management would control spread of the disease and make our food safer and more secure.

While a vaccine without a complementary test would probably generate a modest economic improvement over either of the other scenarios, the risks of unintended market disruptions due to false positives for TB would make this an unattractive strategy. Vaccine producers might like this option, as it reduces their development costs, but producers and governments would find little that attracts them to using this as a major strategy for disease reduction. This approach might work in non-trading countries, but Canada exports such a large portion of its cattle herd annually that this is not a practical option.

Scenario 4: Combining a new vaccine and diagnostic

Utilizing and streamlining vaccine use between trading countries is an important facet of reducing waste, improving economies, and maximizing production. The strategy currently being pursued by the ReVAMP project funded by Genome Canada and undertaken by VIDO-InterVac involves developing a new vaccine with companion diagnostic to distinguish between animals vaccinated for JD and those that are infected with TB. Table 4.6 shows the array of benefits and costs associated with such a strategy.

This scenario has a full array of actors engaged, including dairy producers, governments, companies that produce DIVA tests, vaccine producers, and the public. If the actors can be motivated, the common-pool problem can be managed by the interplay of public, farmer and industry participants.

The benefits to dairy producers associated with alignment and development of a new vaccine and testing tool include: reduced waste due to cull and kill; the potential to develop herd immunity and remove JD from the endemic list of diseases; higher productivity; and lower risk of false positives that might disrupt the marketplace. Ultimately, all of these would work to increase public trust, which Spriggs and Isaac (2007) assert would help with international competitiveness. The main barrier to dairy producers is the cost of vaccinating in small herds as they may not be able to offset costs of utilizing a new vaccine. Small herds often are unable to access adequate veterinary services to fully utilize the new vaccines. There is also the general cost of purchasing the testing kits and vaccines to dairy producers.

DIVA vaccine tests used by government agencies and importers would help to ensure that their product is not infected by disease and that market disruption is not triggered by poor testing. DIVA tests ensure that there is enough specificity in the test being used to differentiate between different diseases; the low specificity of currently used tests is the trigger for false positives for misidentifying JD vaccines as TB infected animals.

Table 4.6: Scenario 4: Developing and aligning testing Differentiating Infection in Vaccinated Animals (DIVA) and new vaccines

Actors	Benefits	Cost
Dairy Producers	<ul style="list-style-type: none"> • Less cull and kill • Lower disease • Higher productivity • Fewer false positives • Public Trust Gained 	<ul style="list-style-type: none"> • Testing Kits • New vaccine purchase
Governments	<ul style="list-style-type: none"> • Decrease in spread of disease, and greater security in international trade 	<ul style="list-style-type: none"> • Administration costs for new testing • Cost of evaluating the program and ensuring compliance
DIVA test Producers	<ul style="list-style-type: none"> • Advanced research and development as competitive advantage • Net revenues 	<ul style="list-style-type: none"> • Risk of producing the good and not being used (adopted) by many dairy farmers to generate profit
Vaccine Producers	<ul style="list-style-type: none"> • Advanced research and development as competitive advantage • Net revenues (royalty) 	<ul style="list-style-type: none"> • Risk of producing the good and not being used by many dairy farmers to generate profit
Public	<ul style="list-style-type: none"> • Less likely for disease to spread • Safe and secured food sources 	<ul style="list-style-type: none"> • Indirect cost when dairy producers do not implement other best management techniques

Benefits to the government include reducing the spread of disease and improved international trade relations. This also would go a long way to securing the economic prospects for the dairy industry, reducing costs for farm support. Additionally, when new vaccines are implemented, and DIVA tests with higher specificity are aligned amongst trading countries, there is less need for quarantine services, and other regulations. Governments would incur some related costs, as when a new vaccine and new test is developed government is mandated to

review and approve its use. Moreover, there may be some costs to the government from dissemination of knowledge to dairy producers of new testing and vaccines.

Both vaccine producers and diagnostic test producers would be motivated to engage. In the context of ReVAMP, the vaccine and diagnostic are being developed as part of the same project by the same entity, but there is no need for that always to be the case. There are sound reasons why these two applications might develop independently, as they appeal to different needs. The vaccine would generate demand from farmers as it delivers improved agronomics and farm-level risk management, while the diagnostic is more directed at the larger industry and government actors. While obviously similarly motivated by revenues, and possibly by the combined increased market value, each generates their value in different parts of the supply chain. There is always the risk that the new vaccines and tests may not realize adequate revenues to compensate for the development costs. As Ugochukwu and Phillips (2018) show, the new vaccine is not universally demanded, and the market clearing prices is quite low.

This scenario offers improved outcomes for consumers. The result of reducing the spread of JD is safer, more nutritious, and more secure milk and related by-products. Since milk (and the meat derived from culled dairy cows) is an important source of nutrition for people of different age brackets globally, alignment of disease testing and production of new vaccination techniques would yield a global benefit.

Overall, this scenario would offer the highest benefit-cost ratio and greatest security. As with all strategies, however, sometimes a blend is optimal. Scenario 5 outlines that option.

Scenario 5: Comprehensive management

Rather than trying to motivate sub-groups to implement or refine one of the four previous strategies, it might be more feasible to motivate all the respective actors—farmers, governments, vaccine and DIVA test producers and the public—to pursue a blended or integrated strategy. In past strategies there were unambiguous winners and losers, which complicates action. While engaging multiple actors sometimes complicates the process, the advantage is that everyone is more likely to contribute if they can see a pay-off, albeit some of those payoffs may have been realized with little or no effort in some of the other scenarios. Table 4.7 lays out the main benefits and costs that would emerge from such an engaged strategy.

Table 4.7: Scenario 5: Developing new vaccine and aligning testing (DIVA) with best management practices

Actors	Benefits	Cost
Dairy Producers	<ul style="list-style-type: none"> • Less cull and kill • Lower disease • Higher productivity • Fewer false positives and related market disruption 	<ul style="list-style-type: none"> • Changing best management practices and related investments to align with new vaccines and new tests
Governments	<ul style="list-style-type: none"> • Decrease spread of disease, and increased security in international trade 	<ul style="list-style-type: none"> • Administration costs for new testing • Cost of evaluating the program and ensuring compliance
Vaccine Producers	<ul style="list-style-type: none"> • Profits • Advanced research and development as competitive advantage 	<ul style="list-style-type: none"> • Risk of the vaccine not being used/adopted by many dairy producers
DIVA Test Producers	<ul style="list-style-type: none"> • Profits • Advanced research and development as competitive advantage 	<ul style="list-style-type: none"> • Risk of the vaccine not being used/adopted by many dairy producers
Public	<ul style="list-style-type: none"> • Less likely for disease to spread, and externalities associated with trade (and the economy) are reduced if testing is updated and innovative 	<ul style="list-style-type: none"> • Small tax or program implications due to government role

The costs and benefits are the same in this situation as scenario 4 without the risk of some farmers no longer using other best management practices. The additional cost to the government is the cost of ensuring compliance.

Individually scenario one to four cannot ensure food security, at least partly because the costs and benefits are not aligned to motivate all the right actors. While the public and consumers will win when JD is controlled, there is no way for all actors to win in these scenarios. The best case that should be implemented is when all actors win. All actors involved will win when diseases are controlled, and food security is preserved. Each of the first four partial scenarios yields various losers. There is no real trend except for the public, who lose in every scenario in various degrees; tax money is used when creating a vaccine and implementing a best management practice, but with remaining liabilities that would rest with citizens and taxpayers. Although scenario five is costly for many of the actors, it is the best case for accomplishing the goal of ensuring food security and balancing the risks and rewards.

Summary of Scenarios

The results of the scenarios are summarized in table 4.8 below. The values were assigned based on the severity of the cost being offset by any benefits. If a specific disease management method had only costs associated with it, it would be a 5 (worst case) and if the costs were not as high as benefits, then the value assigned would be less than 5. When multiple benefits accrue, and little cost was seen then the value would continue to decrease.

The formulation of a vaccine by design will alleviate the issue of false positives. A vaccine that surmounts the problem will have less need for a new diagnostic to differentiate between vaccinated and TB infected animals, however, diagnostics are still a crucial management practice.

While there is no single unambiguously superior strategy that would mobilize and incentivize all the actors to participate with the prospect of improving their lot, the average of the ordinal preferences of the five possible actors suggests that the combined strategy laid out in scenario 5 is feasible, in that it is one of top preferences of each of the actors, such that each has a prospect of improving their circumstances by engaging.

Table 4.8: Ordinal ranking of the net benefits by actor and by strategy (1 = best, 5 = worst)

Actors	Scenario 1 Cull/Kill	Scenario 2 Best Management	Scenario 3 New Vaccines without a DIVA Test	Scenario 4 New vaccines with a new DIVA Test	Scenario 5 Combined strategy
Dairy Producers	5	4	3	1	2
Governments	5	3	4	2	1
Vaccine Producers	5 (tie)	5 (tie)	1	3	2
DIVA Test Producers	5 (tie)	5 (tie)	5 (tie)	1	2
Public	5	4	4	2	1
Average	5	4.2	3.4	1.75	1.6

Section 5:

How to approach JD control through partnership

New vaccines, adoption of best management practices, and new DIVA tests that are more specific, sensitive and able to prevent false-positives, would go a long way to reducing instances of disease and preserve food security. However, without adequate education for producers they may neglect best management practices, and not know about innovations associated with new vaccines and DIVA tests. These educational factors suggest that the feasible pathway to reduced JD requires involvement and collaboration of the different actors in the system including government agencies, veterinarians, and producers of dairy, vaccines, and DIVA tests. Ugochukwu and Phillips (2018) conclude that veterinarians are the key to making this work.

In addition to working with the governments where manufacturing, sale, and testing occurs, vaccines and DIVA producers can also partner with veterinary services to bring the tests and information to producers to reduce animal diseases. Tablet devices are provided in Italy to give farmers access to information and the ability to perform herd-specific support measures. National conferences are also used to promote disease and vaccination awareness. Producers in Canada could work with multiple levels of government to promote peer-to-peer learning and fine tune the incentives for implementing best management practices.

If companies align strategies with that of regulated trade, there would be reduced risk. However, as mentioned earlier, zero risk is next to impossible. Producers working with governments to ensure disease surveillance, biosecurity, traceability, and good management practices are essential to risk control (Garland, and de Clercq, 2011). Governments could also work with universities to train graduates on risk assessment and international trade. Producers could help by issuing transparent documents describing the treatment records of their animals, including factors required to assess the risk involved. Uttenthal et al. (2010) suggest that producers implement a five-year review of vaccines, disease epidemiology, and disease instances. The continuous update of archives and vaccine data will allow for better control of the risk posed by vaccine market externalities (Uttenthal et al., 2010). The sensitivity and specificity of DIVA tests would allow for better risk-management and could alleviate many market externalities when companies work with government and vaccination markets.

Meanwhile DIVA vaccines with companion diagnostics have been reported to be effective in the management of actual infections of diseases like bovine paratuberculosis, infectious bovine rhinotracheitis, foot-and-mouth disease, and pseudorabies (Meeusen et al. 2007). Some European countries already implement this method of testing to reduce the false-positives found with simply using DIVA and paper trails of vaccine, and other information regarding the imported animal or animal product. In the early 1980s, the USA implemented and utilized such test kits (Lee, Senne, and Suarez, 2004).

At the same time, manufacturers could make more effort to use the internet to disseminate information on their products and their uses by participating in social media groups, subscription memberships, and other big-data users. Manufacturers could also work with the government to ensure registered producers have access to internet services to access this information by using information on purchased cattle, and other means of information collection (Smyth, McDonald, and Falck-Zepeda, 2014).

The economic losses experienced through ineffective DIVA diagnostics should serve as an incentive to farmers and other agents in the bovine vaccine market to innovate and foster implementation of policy consistent with a multi-pronged approach to bovine JD eradication. Additionally, manufacturers can successfully commercialize vaccines due to the epidemiological affirmation in a competitive market (Bioprocess International, 2008). Availability, affordability, and accessibility denote an accepting market. In terms of JD in Canada, there is much to be desired in terms of availability to rural communities: supplementing vaccines with infrastructure to access closed-off markets will increase commercialization viability. Governments may need to offer subsidies (possibly linked to regulatory compliance) in order to ensure uptake and use by small and rural herds. Otherwise, there may be no way for a small-sized farm to adopt new vaccines and adhere to management practices needed to control JD.

The risk analysis framework as it relates to bio-safety policy is an effective tool to determine how farmers can choose to adopt vaccinations or other forms of disease control methods (Phillips and Smyth, 2018). Historically, agriculture has made efforts to evolve and adapt to changing environments of risk. Communication of risk through information exchanges leads to greater receptiveness of mitigating factors of that risk. This is evident when producers and farmers are aware of the dangers and possible losses; they are more likely to participate in disease control measures such as vaccinations, and best management practices.

Test and cull, vaccination, and management practices alone would appear to be ineffective at dealing with JD, but together with information access, there is hope of preventing further economic and public good losses (Roth 2011). In order to spur governments, bovine and vaccine producers, and veterinarian services into action to tackle the issue of JD, a catalytic agent may be necessary. While market disruption is one form of catalytic pressure, it would be better public policy if decision-makers and street-level bureaucrats were to anticipate and proactively address these risks. It has been theorized that many governments have the necessary catalytic agents within their structures - the street level bureaucrat. A public entrepreneur, perhaps the chief veterinarian, could be the agent that could start the conversation on improving and updating methods to control the diseases mentioned (Tummers, and Bekkers, 2014). These agents are in the field and have the contacts required to initiate the process, however, there are limitations on what that any single agent might accomplish. In order to maximize the chances of success, these street level bureaucrats will need to utilize windows of opportunity that arise from any noise made in the dairy space, or other political events that put a focus on the change needed in the regulatory space.

Section 6:

Conclusions

Milk— a commodity consumed in many countries and economies—is an integral part of food security in the world. With growing populations there is a need for complete and adequate nutritious foods and milk is one commodity that provides essential nutrients – calcium, protein, iodine, potassium, phosphorus and vitamins B2 and B12. Diseases in milk-producing animals, such as bovines, however, threaten food security. JD is a threat to milk security as it is an endemic disease that affects a large proportion of milk-supplying countries. This poses a cost and risk to the general public, and producers that are an integral part of the economy.

In this thesis, the mechanisms used by regulatory bodies in North America and a few key foreign countries that export and import milk products in controlling JD are explored. The problem was framed using the IAD framework to show the actors and institutions involved, the scope of good JD management and how the various actors and institutions implement solutions via the political feasibility theory. This set up the way in which solutions could be formulated.

The potential solutions to JD control were described using different scenarios. Scenario 1 showed that the cull-and-kill method will have many costs to producers of dairy, vaccine and DIVA test, the public, and government, with little added benefit. Improved management practices illustrated in scenario 2 had a similar problem as scenario 1, but with the added issue of unregulated compliance. Using vaccines alone (scenario 3) would not be sufficient to solve the false-positive problem that triggers quarantines and loss of production, while using new vaccines with a new DIVA test (scenario 4) could result in farmers neglecting other good management practices. The proposed solution that would benefit the most and lead to the intended goal of food security and reduced economic loss is a combination of new vaccines, new DIVA tests, and aligned best management practices.

In order to effectively achieve this type of solution, many actors will have to work together in partnership. Vaccine producers, veterinarians, DIVA test producers, the government and farmers will need to collaborate to ensure that best management practices are aligned, which would include the use of vaccines and DIVA tests. The government’s policy-makers and street-level-bureaucrats will need to work closely with the private market.

6.1 Policy Implications

I assert that many actors involved in the proposed solution must act in unison. If the government wants to preserve food security and consumer confidence, then regulatory agencies must ensure that new vaccine and DIVA testing products are widely available and educational materials are provided to farmers. As noted earlier by Ugochukwu and Phillips (2018), there are many dairy producers who would be early adopters, and others that would utilize new vaccines and tests if the prices are affordable. There is another group that would require incentives to pursue changes to their engrained management practices. These groups could be incentivized in a variety of ways, such as with subsidies provided by government, or they could simply be motivated through educational programs managed by government and veterinarians that show them the costs and benefits of adopting aligned management practices with new vaccines and DIVA tests. Vaccine developers should be willing partners, as they will want to ensure that their product can be successfully adopted by end users by engaging with veterinarians, dairy producers, and governments.

6.2: Extensions

For any scholar wishing to build upon this work, I suggest reframing the problem to determine whether JD is still a major impediment to food security, to assess why government has or has not added it to the list of reportable or immediately identifiable diseases, and to challenge whether vaccines are necessarily part of the solution set.

References

- Agriculture and Agri-Food Canada. "D035 Exports of Dairy Products by Country of Destination." Exports of Dairy Products by Country of Destination - Agricultural Industry Market Information System (AIMIS) - Agriculture and Agri-Food Canada (AAFC), 10 Dec. 2018, aimis-simia-cdic-ccil.agr.gc.ca/rp/index-eng.cfm?action=gR&r=139&signature=F793ABD8773F4031CB90ADAB7CA7BF29&pdtc=&pTpl=1#wb-cont.
- Alberta Agriculture and Forestry, Livestock and Crops Division. "Agri-Facts." *Alberta Agriculture and Forestry*, 13 May 2015, <https://open.alberta.ca/dataset/fe445e63-a701-475b-b9f4-db5b39ec403c/resource/4b7dfd78-8d79-4d5a-8a23-251c119281d4/download/2015-663-15.pdf>
- Alberta Agriculture and Forestry, Livestock and Crops Division. "John's Disease." *Alberta Agriculture and Forestry*, 13 May 2015, [www1.agric.gov.ab.ca/\\$department/deptdocs.nsf/all/agdex742](http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/agdex742).
- "Background Information: OIE – World Organisation for Animal Health." *OIE*, www.oie.int/scientific-expertise/registration-of-diagnostic-kits/background-information/.
- Baker, R., and E. Empringham. Optimising Canadian Dairy Farm Biosecurity. Canadian John's Disease Initiatives, 2013, Optimising Canadian Dairy Farm Biosecurity, www.animalhealth.ca/aspx/public/publicdocs/CJDITransitionToBio.pdf.
- Bannantine, J. P., and A. M. Talaat. "Controlling John's Disease: Vaccination Is the Way Forward." *Frontiers in Cellular and Infection Microbiology*, vol. 5, 2015, doi:10.3389/fcimb.2015.00002.
- Barkema, Herman, Karin Orsel, Caroline Ritter, Jesse Schuster, Caroline Corbett, Roert Wolf, Steve Roche, Cathy Bauman, Ronald Barker, G. Fecteau, C. Luby, Greg Keefe, Shawn McKenna, John Kastelic, Jeroen De Buck, and David Kelton. "Lessons Learned from the Canadian John's Disease Program." *WCDS Advances in Dairy Technology*, vol. 30, 2018, pp. 310.
- Bastida, F., and R. A. Juste. "Paratuberculosis Control: A Review with a Focus on Vaccination." *Journal of Immune Based Therapies and Vaccines*, vol. 9, 2011, pp 8.

- Bell, David. "Investigation into Alberta Bovine TB Outbreak Wraps up CBC News." *CBC News*, CBC/Radio Canada, 11 May 2018, www.cbc.ca/news/canada/calgary/investigation-bovine-tb-outbreak-wraps-up-1.4658492.
- BioProcess International, 2008. "Global Vaccine Commercialization. BPI's State of the Industry: Perspectives from inside the bio-manufacturing industry".
- Caldow, G., and D. Henderson. *Assessment of Surveillance and Control of Johne's Disease in Farm Animal in Great Britain – Chapter 6*. Veterinary Division of the Scottish Agricultural College. SAC Veterinary Science Division, 2002.
- Caldow, G. L., J. C. Low, and G. J. Gunn. "Control Programmes for Johne's Disease in Cattle: An International Review." *Irish Veterinary Journal*, vol. 56, no. 6, 2003, pp. 304-308.
- Capua, H., C. Terregino, G. Cattoli, F. Mutinelli, and J. F. Rodriguez. "Development of a DIVA Strategy Using a Vaccine Containing a Heterologous Neuraminidase for the Control of Avian Influenza," *Avian Pathology*, vol. 32, 2002, pp. 47.
- Çetinkaya, B, H. M. Erdogan, K. L. Morgan. "Relationships between the Presence of Johnes Disease and Farm and Management Factors in Dairy Cattle in England." *Preventive Veterinary Medicine*, vol. 32, no. 3-4, 1997, pp. 253–266.
- Chiodini, R. J., H. J. Van Kruiningen, and R. Merkal. "Ruminant Paratuberculosis (Johne's Disease): The Current Status and Future Prospects." *Cornell Veterinarian*, vol. 74, no. 3, 1984, pp. 218-262.
- Collins, T. M. and R. I. Morgan. "Economic decision analysis model of a paratuberculosis test and cull program." *Journal of the American Veterinary Medical Association*, vol. 199, no. 12, 1991, pp.1724-1729.
- Constable, P. D., K. W. Hinchcliff, S. H. Done, and G. Walter. *Veterinary Medicine: A Textbook of the Diseases of Cattle, Horses, Sheep, Pigs and Goats*. Saunders, 2017.
- Corbett, C. S., S. A. Naqvi, C. A. Bauman, J. De Buck, K. Orsel, F. Uehlinger, D. F. Kelton, and H. W. Barkema. "Prevalence of Mycobacterium Avium Ssp. Paratuberculosis Infections in Canadian Dairy Herds." *Journal of Dairy Science*, vol. 101, no. 12, 2018, pp. 11218.
- Donat, K., A. Soschinka, G. Erhardt, and H. R. Brandt. "Paratuberculosis: decrease in milk production of German Holstein dairy cows shedding Mycobacterium avium ssp. paratuberculosis depends on within-herd prevalence." *Animal*, vol. 8, no. 5, 2014, pp. 852-858.

- Dorshorst, N. C., M. T. Collins, and J. E. Lomard. "Decision analysis model for paratuberculosis control in commercial dairy herds." *Preventive Veterinary Medicine*, vol. 75, 2006, pp. 96-122.
- Draayer, H. "Overview of Currently Approved Veterinary Vaccine Potency Testing Methods in development that do not Require Animal Use." *Procedia in Vaccinology*, vol. 5, pp. 171-174.
- Dufour, B., R. Pouillot, and B. Durand. "A Cost/Benefit Study of Paratuberculosis Certification in French Cattle Herds." *Veterinary Research*, vol. 35, no. 1, 2004, pp. 71.
- Espejo, L.A., S. Godden, W.L. Hartmann, and S.J. Wells. "Reduction in incidence of Johne's disease associated with implementation of a disease control program in Minnesota demonstration herds," *Journal of Dairy Science*, vol. 95, no. 7, 2012, pp. 4141.
- Feller, M., K. Huwiler, R. Stephan, E. Altpeter, A. Shang, H. Furrer, G. E. Pfyffer, T. Jemmi, A. Baumgartner, and M. Egger. "Mycobacterium Avium Subspecies Paratuberculosis and Crohn's Disease: A Systematic Review and Meta-Analysis." *The Lancet Infectious Diseases*, vol. 7, no. 9, 2007, pp. 607.
- Food and Agriculture Organization of the United Nations, "The Global Dairy Sector: Facts." 2014, www.fil-idf.org/wp-content/uploads/2016/12/FAO-Global-Facts-1.pdf.
- Foreign Affairs Trade and Development Canada and Corporate Affairs. "Canada-United States-Mexico Agreement (CUSMA)." GAC, 6 Dec. 2018, www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cusma-aceum/index.aspx?lang=eng.
- Garcia, A. B., and L. Shalloo. "Invited Review: The Economic Impact and Control of Paratuberculosis in Cattle." *Journal of Dairy Science*, vol. 98 no. 8, 2015, pp. 5019.
- Garland, A. J. M., and K. de Clercq. "Cattle, Sheep, and Pigs Vaccinated Against Foot and Mouth Disease: Does Trade in These Animals and their Products Present A Risk of Transmitting the Disease?" *Review Science Technology Office of International Epizootology*, vol. 30 no. 1, 2011, pp. 189-206.
- Garrido, J., P. Vazquez, E. Molina, J. M. Palazoala, I. A. Sevilla, M. V. Geijo, M. Alonso-Hearn, and R. A. Juste. "Paratuberculosis Vaccination Causes Only Limited Cross-Reactivity in the Skin Test for Diagnosis of Bovine Tuberculosis." *PLoS One*, Vol8, no. 11, 2013, doi: 10.1371/journal.pone.0080985.

- Government of Canada, Canadian Dairy Information Centre. "Canada's Dairy Industry at a Glance." Canadian Dairy Information Centre (CDIC), 26 Mar. 2018, www.dairyinfo.gc.ca/index_e.php?s1=cdi-ilc&s2=aag-ail.
- Government of Canada, Canadian Food Inspection Agency, and Animal Health Directorate. "Federally Reportable Diseases in Canada - 2018." 6 Dec. 2018, www.inspection.gc.ca/animals/terrestrial-animals/diseases/reportable/2018/eng/1329499145620/1329499272021.
- Gutierrez, A., D. Spreo, C. Gay, M. Zimic, and A. S. De Groot "New Vaccines Needed for Pathogens Infecting Animals and Humans: One Health." *Human Vaccines & Immunotherapeutics*, vol. 8, no. 7, 2012, pp. 971-978.
- Hendrick, S. H., D. F. Kelton, K. E. Leslie, K. D. Lissemore, M. Archambault, and T. F. Duffield. "Effect of Paratuberculosis on Culling, Milk production, and Milk Quality in Dairy Herds." *Journal of the American Veterinary Medical Association*, vol. 227, 2005, pp. 1302-1308.
- Hendricks, S., and D. Douma. "Literature Review of Johne's Disease in Beef Cattle." *Albert Beef Producers*, 2006.
- Hess, C., and E. Ostrom. "A Framework for Analysing the Microbiological Commons." *International Social Science Journal*, vol. 58, no. 188, 2006, pp335-349.
- "Johne's Disease." *Beef Cattle Research Council*, Beef Cattle Research Council, 29 June 2018, 2:06 AM, www.beefresearch.ca/research-topic.cfm/johnes-disease-51.
- Johnson, Y. J., J. B. Kaneene, J. C. Gardiner, J. W. Lloyd, D. J. Sprecher, and P. H. Coe. "The Effect of Subclinical Mycobacterium Paratuberculosis Infection on Milk Production in Michigan Dairy Cows." *Journal of Dairy Science*, vol. 84, 2001, pp. 2188-2194.
- Kelton, D.F., C Ritter, S. Roche, and H. Barkema. "Johne's Disease Control in Canada 2014-2016: Prevalence, Status Program and Communication," (Forum, 5th ParaTB Forum, International Dairy Federation, Nantes, France, June 19, 2016.)
- Kennedy, A., N. Byrne, A. Garcia, J. O'Mahony, and R. Sayers. "Analysis of Johnes Disease ELISA Status and Associated Performance Parameters in Irish Dairy Cows." *BMC Veterinary Research*, vol. 12, no. 43, 2016.

- Lee, C., D. A. Senne, and D. L. Suarez, "Generation of Reassortant Influenza Vaccines by Reverse Genetics That Allows Utilization of a DIVA Strategy for the Control of Avian Influenza," *Elsevier Ltd*, Vol. 22, 2004, pp. 3175-3183.
- Liu, M., J. M. Wood, T. Ellis, S. Krauss, P. Seiler, J. Christie, E. Hoffmann, J. Humberd, D. Hulse, Y. Zhang, R. Webster, and D. Perez. "Preparation of a Standardized, Efficacious Agricultural H5N3 Vaccine by Reverse Genetics." *Virology*, vol. 314, 2003, pp. 580-590.
- Lombard, J. E., B. McCluskey, B. Wagner, and F. Garry. "Risk of Removal and Effects on Milk Production Associated with Paratuberculosis Status in Dairy Cows." *Journal of the American Veterinary Medical Association*, vol. 12, 2005, pp. 1975-1981.
- Mackay, D. K. J., M. A. Forsyth, P. R. Davies, A. Berlinzani, J. F. Belsham, M. Flint, and M. D. Ryan. "Differentiating Infection from Vaccination in Foot and Mouth Disease Using a Panel of Recombinant, Non-Structural Proteins in ELISA." *Vaccine*, vol. 16, no. 5, 1998, pp. 446-459.
- Mahoney, J. T. "The Choice of Organizational Form: Vertical Financial Ownership Versus Other Methods of Vertical Integration." *Strategic Management Journal*, Vol. 13, No. 8, 1992, pp. 559-584.
- Majone, G. "On the notion of political feasibility." *European Journal of Political Research*, vol. 3, no. 3, 1975, doi: <https://doi.org/10.1111/j.1475-6765.1975.tb00780.x>
- Mckenna, S. L. B., G. P. Keefe, H. W. Barkema, J. McClure, P. Hanna, and D. C. Sockett. "Cow-Level Prevalence of Paratuberculosis in Culled Dairy Cows in Atlantic Canada and Maine." *Journal of Dairy Science*, vol. 87, no. 11, 2004, pp. 3770– 3777.
- McKenna, S. L.B., G. P. Keefe, A. Tiwari, J. Vanleeuwen, and H. Barkema. "Johne's Disease in Canada Part II: Disease Impacts, Risk Factors, and Control Programs for Dairy Producers." *The Canadian Veterinary Journal*, vol. 47, no. 11, Nov. 2006, p. 1092.
- Mee, J. F., and E. Richardson. "Epidemiology and Economic Impact of Johne's Disease in Irish Dairy Herds." End of Project Report, Teagasc, 2008.
- Meeusen, E., J. walker, A. Peters, P. Pastoret, and G. Jungersen. "Current Status of Veterinary Vaccines." *Clinical Microbiology Reviews*, vol. 20, no. 3, 2007, pp. 491-495.
- Meyer, A. L., and H. H. Hall. "Economic Analysis of the Impact of Paratuberculosis on the Kentucky Cattle Industry." *Department of Agricultural Economics*, Staff paper #343, 1994.

- Milstien, J. B., M. Kaddar, and M. Kieny, "The Impact of Globalization on Vaccine Development and Availability," *Health Affairs*, vol. 25 no. 4, 2006, pp. 1061-1069.
- O'Doherty, A., D. O'Grady, J. Egan, T. Smith, and K. J. O'Farrell. "Survey of Johne's Disease in Imported Animals in the Republic of Ireland." *The Veterinary Record*, vol. 150, no. 20, 2002, pp. 634.
- Ochieng, B. J., and J. E. Hobbs. "Incentives for Cattle Producers to Adopt an E. Coli Vaccine: An Application of Best-Worst Scaling." *Food Policy* vol. 59, 2016, pp. 78.
- Ostrom, E. *Understanding Institutional Diversity*. Princeton University Press, 2005.
- Phillips, P. W. B. "The Kaleidoscope of Risk Analysis: The state of the art 25 years after the Red Book." Commentary on the proceedings of the 1st International Conference on Risk Assessment, Brussels, 2009.
- Phillips, P. W. B., and S. J. Smyth. "The Risk Analysis Framework and Biosafety Policy." *Genetically Modified Organisms in Developing Countries*, 2018, pp. 153–161., doi:10.1017/9781316585269.014.
- Pillars, R. B., M. W. Bolton, and D. L. Grooms. "Case-control study: Productivity and longevity of dairy cows that tested positive for infection with *Mycobacterium avium* ssp. paratuberculosis as heifers compared to age-matched controls." *Journal of Dairy Science*, 2011, pp. 2825-2831.
- Raizman, E. A., J. Fetrow, S. J. Wells, S. M. Godden, M. J. Oakes. "The Associations Between Culling Due to Clinical Johne's Disease or the Detection of *Mycobacterium avium* subsp. Paratuberculosis Fecal Shedding and the Diagnosis of Clinical or Subclinical Diseases in Two Dairy Herds in Minnesota, USA." *Preventative Veterinary Medicine*, vol. 80, 2007, pp. 166.
- Rossiter, C. A., and W. S. Burhans. "Farm-Specific Approach to Paratuberculosis (Johne's Disease) Control." *Veterinary Clinics of North America: Food Animal Practice*, vol. 12, no. 2, 1996, pp. 383–415.
- Roth, J. A. "Veterinary Vaccines and their Importance to Animal Health and Public Health." *Procedia in Vaccinology*, vol. 5, 2011, pp. 127-136.
- Schaik, G., C. H. J. Kalis, G. Benedictus, A. A. Dijkhuizen, and R. B. M. Huirne. "Cost-benefit analysis of vaccination against paratuberculosis in dairy cattle." *Veterinary Record*, vol. 139, no. 25, 1996, pp. 624-627.

- Scott-Orr, H., R. E. Everett, S. J. Ottoway, and R. N. North. "Estimation of Direct and Indirect Losses Due to Johne's Disease in New South Wales, Australia." *Acta Veterinaria Scandinavica, Supplementum*, vol. 84, 1988, pp. 411-414.
- Seitzinger, A.H., K.W. Forsythe Jr., and M.L. Madell. "Regionalization's Potential in Mitigating Trade Losses Related to Livestock Disease Entry." *Annals of the New York Academy of Sciences*, vol. 894, 1999, pp. 95-99.
- Sibley, D., and P. Orpin, "The National Johne's Management Plan in the UK Dairy Herd," (Forum, 5th ParaTB Forum, International Dairy Federation, Nantes, France, June 19, 2016.)
- Socketk, D. C., D. J. Carr, and M. T. Collins. "Evaluation of Conventional and Radiometric Fecal Culture and a Commercial DNA Probe for Diagnosis of Mycobacterium Paratuberculosis Infections in Cattle." *Canadian Journal of Veterinary Research*, vol. 52, no. 2, 1992, pp. 153.
- Smyth, S.J., J. McDonald., and J. Falck-Zepeda. "Investment, Regulation, and Uncertainty: Managing New Plant Breeding Techniques." *GM Crops Food*, vol. 4, no. 1, 2014, pp. 44-57.
- Spriggs, J., and G. Isaac. *Food Safety and International Competitiveness: The Case of Beef*. Cabi, 2007.
- Stephenson, A. "10 Years Later: How the Mad Cow Crisis Changed an Industry and a Province (with Videos)." *Www.calgaryherald.com*, 27 May 2013, www.calgaryherald.com/business/years-later-crisis-changed-industry-province-with-videos/8405721/story.html.
- Sutmoller, P., and R. C. Olascoaga. "The Risks Posed by the Importation of Animals Vaccinated Against Foot and Mouth Disease and Products Derived from Vaccinated Animals: A Review," *World Organization for Animal Health*, vol. 22, no. 3, 2003, pp. 823-835. Accessed November 11, 2017.
- Tiwari, A., J. A. VanLeeuwen, I. R. Dohoo, G. P. Keefe "Estimate of the Direct Production Losses in Canadian Dairy Herds with Subclinical Mycobacterium Avium Subspecies Paratuberculosis Infection." *The Canadian Veterinary Journal*, vol. 49, no. 6, 2008, pp. 569-576.

- The United States Department of Agriculture. “Dairy 2014: Dairy Cattle Management Practices in the United States” Fort Collins, February 2016, pp. i-99.
- The United States Department of Agriculture “Johne's Disease.” USD APHIS | *Research Facility Annual Summary Report*, 18 Aug. 2017,
www.aphis.usda.gov/aphis/ourfocus/animalhealth/nvap/NVAP-Reference-Guide/Control-and-Eradication/Johnes-Disease.
- Thomson, G.R., E. N. Tambi, S. K. Hargreaves, T. J. Leyland, A. P. Catley, G. G. M. van T Klooster, and M. L. Penrith. “International Trade in Livestock and Livestock Products: The Need or a Commodity-Based Approach.” *The Veterinary Record*, vol. 155, 2004, pp. 429-433.
- “Tuberculosis (TB).” World Health Organization, World Health Organization, 2 Jan. 2019,
www.who.int/tb/en/.
- Tummers, L.G., and V.J.J.M. Bekkers. “Policy implementation, street-level bureaucracy and the importance of discretion.” *Public Management Review*, vol. 16, no. 4, 2014, pp. 527-547.
- Ugochukwu, A. I., and P. W.B. Phillips. “Farmers’ Attitude Towards Animal Vaccines: A Quantitative Analysis of Beef and Dairy Farmers in Canada.” Accessed February 10, 2018.
- UK House of Commons Environment, Food and Rural Affairs Committee. “Vaccination Against Bovine TB: Second Report of Session 2013-14.” Vol. 1, 2013.
- Uttenthal, Å., S. Parida, T. B. Rasmussen, D. J. Paton, B. Haas, W. G. Dundon. “Strategies for Differentiating Infection in Vaccinated Animals (DIVA) for Foot-and-Mouth Disease, Classical Swine Fever and Avian Influenza.” *Expert Review of Vaccines*, vol. 9, no. 1, 2010, pp. 73–87., doi:10.1586/erv.09.130.
- VanLeeuwen, J., G. P. Keefe, R. Tremblay, C. Power, and J. J. Wichtel. “Seroprevalence, Spatial Distribution and Productivity Effects of Infection with Johne’s Disease and Bovine Leukosis in Maritime Canadian Dairy Cattle.” *The 9th International Symposium on Veterinary Epidemiological Economics*, Breckenridge, CO, USA, pp. 1-3.
- Weber-Vintzel, L. “Revision of the Standard Operating Procedures for the Official Recognition of Disease Status.” *The OIE Sixth Strategic Plan*, 2010.
- Westenhöfer, J. “Energy Density and Cost of Foods in Germany,” *Ernaehrungs Umschau international*, vol. 60 no. 3, 2013, pp. 30–35.

- Whitlock, R. H., and C. Buergelt. "Preclinical and Clinical Manifestations of Paratuberculosis (including Pathology)." *Veterinary Clinics of North America: Food Animal Practice*, vol. 12, no. 1, 1996, pp. 345-356.
- Whittington, R. J., and E. Sergeant. "Progress Towards Understanding the Spread, Detection and Control of Mycobacterium Avium Subsp Paratuberculosis in Animal Populations." *Australian Veterinary Journal*, vol. 79, no. 4, 2001, pp. 267-278.